UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY and MANULIFE INSURANCE COMPANY,

CIVIL ACTION NO. 05-11150-DPW

Plaintiffs,

v.

ABBOTT LABORATORIES,

Defendant.

ABBOTT'S POST-TRIAL PROPOSED ADDITIONAL AND SUBSTITUTE FINDINGS OF FACT AND CONCLUSIONS OF LAW

Defendant Abbott Laboratories ("Abbott") respectfully submits the following Post-Trial Proposed Additional or Substitute Findings of Fact and Conclusions of Law for consideration and adoption by the Court at the trial of this action. Abbott reserves the right to supplement or amend these Post-Trial Proposed Findings and Conclusions at a later time, as Abbott deems necessary, as a result of further submissions or proceedings in this action. For the convenience of the Court, the paragraph numbers in Abbott's Post-Trial Proposed Additional and Substitute Findings of Fact and Conclusions of Law correspond to the paragraph numbers of Plaintiffs' Preliminary Proposed Findings of Fact and Conclusions of Law. Abbott also has added as additional conclusions of law paragraphs 73-78, which are not addressed by Hancock's Preliminary Proposed Findings of Fact and Conclusions of Law.

I. PROPOSED FINDINGS OF FACT

Background Facts

The Plaintiffs

- 1. No proposed additional or substitute findings.
- 2. No proposed additional or substitute findings.
- 3. No proposed additional or substitute findings.
- 4. No proposed additional or substitute findings.

The Defendant

- 5. No proposed additional or substitute findings.
- 6. No proposed additional or substitute findings.
- 7. No proposed additional or substitute findings.

The Negotiation of the Research Funding Agreement

- 8. No proposed additional or substitute findings.
- 9. No proposed additional or substitute findings.
- 10. <u>Proposed Substitute Findings</u>: In early 2000, Abbott and Hancock began discussions regarding a potential investment by Hancock in a portfolio of new pharmaceutical compounds that Abbott had under development.
 - 11. No proposed additional or substitute findings.
- 12. Proposed Substitute Findings: Abbott was interested in a potential funding agreement with Hancock for general risk sharing and risk mitigation purposes. Abbott had already spent over half a billion dollars of its own funds developing the compounds that were included in the Research Funding Agreement ("RFA" or "Agreement"). Abbott planned to spend in excess of an additional \$1 billion developing the compounds through 2005. Hancock, in turn, was seeking to commit a portion of its

investment portfolio to an investment with above-average risks and returns. Hancock was aware before the RFA was entered into that pharmaceutical drug development is an inherently risky business and that most pharmaceutical compounds, especially those in early phases of discovery and development, generally do not make it to market.

- 13. Proposed Substitute Findings: Over time, the parties began to concentrate their discussions on an investment structure whereby Hancock would invest approximately \$50 million per year over a four-year period to fund the development of a specified "basket" of pharmaceutical compounds in Abbott's then current research and development portfolio. There was no fixed number of compounds to be included in the portfolio and the number of proposed compounds varied during the course of negotiations. Abbott offered Hancock a selection of compounds in different stages of development pursuant to Hancock's request, including compounds such as ABT-773, ABT-594, and ABT-518, which Abbott considered among the most valuable of the dozens of compounds in its portfolio. ¹
- 14. <u>Proposed Additional Findings</u>: Hancock wanted to invest in a portfolio of compounds at different stages of development, including higher-risk, early stage compounds. Hancock wanted to invest in a portfolio that included "high risk" compounds, because they offered greater potential "upside."
 - 15. No proposed additional or substitute findings.
 - 16. No proposed additional or substitute findings.

¹ Pursuant to the Court's request, Abbott has italicized new proposed findings of fact that were added to or changed from Abbott's Preliminary Proposed Additional or Substitute Findings of Fact and Conclusions of Law.

17. Proposed Substitute Findings: Hancock knew that ABT-594 and ABT-518 might be terminated in the near future. For example, Hancock knew that ABT-518 was part of a class of novel cancer compounds, and that because it involved "a new untried strategy for everyone, it is high risk." Hancock also knew that the risk was compounded by the fact that "most [compounds in the class] are not yet in clinical trials" and "the probability of a particular compound reaching the marketplace is low." When Hancock's senior management approved the investment, it estimated that the probability of success of ABT-518 was only 10 percent. Abbott also disclosed to Hancock in the RFA that compounds in the same class had not demonstrated efficacy and had side effects and that ABT-518:

will need to demonstrate a meaningful clinical advantage over compounds that are in more advanced development. Strict Go/No Go criteria will determine if [ABT-518] can meet these hurdles. If they cannot be met, the compound will not move forward.

Abbott also disclosed in the third paragraph of the ABT-594 Descriptive Memorandum that it would make a "Go/NoGo decision" regarding the compound in June 2001.

Hancock also knew that even compounds at more advanced stages of development and a relatively high estimated probability of success, such as ABT-773, might be terminated for scientific or commercial reasons.

- 18. <u>Proposed Substitute Findings</u>: John Hancock requested that Abbott disclose certain material information regarding the compounds that were to be included in its proposed deal with Abbott, in order to understand and evaluate the deal.
- 19. <u>Proposed Substitute Findings</u>: Hancock and its point person on the deal, Stephen Blewitt, "had substantial experience in evaluating" potential investments in the pharmaceutical industry including investment in compounds under development. In the

course of evaluating those prior investments, Mr. Blewitt and Hancock established relationships with reliable scientific advisors, including Dr. Lynn Klotz, and became experienced in conducting due diligence regarding pharmaceutical products and compounds under development. In evaluating the potential Abbott deal, Hancock conducted its own due diligence. It retained Dr. Klotz to conduct an independent analysis of the proposed compounds. Dr. Klotz conducted a review of publicly available scientific literature relevant to the compounds, including "search[ing] the major drug and medical databases for scientific reports of Program Compounds and competitive [compounds in the same] class or same disease category." Dr. Klotz also interviewed specialists in particular disease areas to gather additional information relevant to the Program Compounds. Dr. Klotz gathered information from independent experts regarding the status of competitor's clinical trials. Dr. Klotz provided information to Hancock regarding the risks associated with each of the compounds.

After conducting due diligence, Hancock interviewed John Leonard, Abbott's Vice President of Development, to ask follow-up questions. Dr. Klotz concluded that his "questions were answered satisfactorily" and that there was "certainly no indication of any deception on Abbott's part." In recommending approval of the deal, Mr. Blewitt stated to Hancock senior management that "[o]ur due diligence provided us with results consistent with Abbott's representations and expectations for the Program Compounds. . . ." For example, with respect to ABT-773, Mr. Blewitt reported: "Our scientific consultant, Robert C. Moellering, Jr., Harvard Medical School and Beth Israel Medical Center, confirmed the scientific rationale for ketolides and their market potential.

Case 1:05-cv-11150-DPW

- 20. Proposed Substitute Findings: During negotiations, Abbott provided Hancock with drafts of Descriptive Memoranda regarding each of the Program Compounds. The Descriptive Memoranda were created by Abbott employees, including the development teams for the particular compound for which the Descriptive Memorandum was created.
- 21. Proposed Substitute Findings: It would not have been practical for Abbott to disclose every piece of data regarding the Program Compounds, and Abbott was not required by the RFA to do so. However, the Descriptive Memoranda, as well as the Annual Research Plans ("ARPs"), attached to the RFA contain the material information regarding the status and prospects of each compound and span dozens of pages. Mr. Blewitt did not provide copies of the draft or final versions of the Descriptive Memoranda or ARPs to Mr. Hartz or members of Hancock's Bond and Investment Committee and Committee of Finance.
- 22. Proposed Substitute Findings: Drafts of the Descriptive Memoranda created by Abbott employees were circulated to more senior Abbott management personnel, including Dr. Leonard, for review before they were sent to Hancock.
- 23. Proposed Additional Findings: During negotiations, Abbott also provided Hancock with drafts of its first annual ARP, which included information regarding Abbott's objectives, activities, timetable, and budget on for the Research Program.
 - 24. Proposed Substitute Findings: See supra, ¶ 19; infra, ¶ 32.
- 25. Proposed Substitute Findings: Abbott personnel involved with the deal with Hancock understood that Hancock desired information regarding Abbott's spending objectives and budget on the Program Compounds during the four-year Program Term

and, therefore, agreed in the RFA to provide Hancock each year with ARPs that would set forth "a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for every Program Year." The first annual ARP was attached as an exhibit to the RFA.

- 26. <u>Proposed Additional Findings</u>: Dr. Klotz only reviewed initial drafts of the Descriptive Memoranda. After July 2000, Hancock did not provide Dr. Klotz with any documents or information. Dr. Klotz did not review the November 2000 or February 2000 drafts of the Descriptive Memoranda, or the final versions attached to the RFA. Hancock also did not provide Dr. Klotz with Abbott's first annual ARP.
- 27. Proposed Substitute Findings: Hancock personnel prepared a detailed computer model, known as a "Monte Carlo" simulation, that Hancock used to develop financial projections for the proposed deal with Abbott. Hancock used certain information provided by Abbott to prepare the Monte Carlo simulation, such as "the general category that [the compounds] were in" (e.g., anti-infective or analgesic), and "the phase they were in" (e.g., preclinical, Phase I, Phase II, or Phase III). Other information utilized by Hancock was obtained by Hancock from public sources. For example, Hancock's estimate of the anticipated commercial launch date for each compound was based on publicly available studies by Dr. Joseph A. DiMasi of the Tufts Center for the Study of Drug Development regarding the average time to launch for compounds in various stages of development. Similarly, Hancock estimated the peak sales for each compound by "look[ing] at industry data for either similar compounds or compounds being developed." Although Abbott had provided Hancock with its own estimates of peak sales for the compounds in early stages of the negotiations, Hancock

did not rely on Abbott's estimates and instead built its own number based on industry data. For estimated probability of success, Hancock relied upon publicly available studies regarding the probability of success for various types of compounds in different phases of development.

- 28. No proposed additional or substitute findings.
- 29. <u>Proposed Additional Findings</u>: Using its independently developed assumptions and the royalty rates anticipated to be included in the agreement, Hancock calculated the estimated milestone and royalty payments that it would receive, its estimated risk of loss on the transaction, and its estimated annual rate of return on the transaction.
- 30. <u>Proposed Additional Findings</u>: Hancock estimated the peak sales for each compound by "look[ing] at industry data for either similar compounds or compounds being developed." In general, Hancock's estimated level of peak sales was significantly below Abbott's level (approximately 25%). To project ramp-up and ramp-down of sales, Hancock utilized a publicly available "Sales Curve" prepared by Lehman Brothers.
- 31. <u>Proposed Substitute Findings</u>: The compounds in the basket of compounds discussed between Abbott and Hancock changed numerous times over the course of the negotiations and the elimination and/or substitution of one or more compounds would not necessarily have a significant adverse impact on the results of that analysis.
- 32. <u>Proposed Additional Findings</u>: Abbott did not make any representations to Hancock in the RFA regarding Hancock's expected returns on the investment or expected sales of the Program Compounds. *The RFA expressly states that*

"[n]otwithstanding anything in this Agreement to the contrary, Abbott does not represent, warrant or guarantee that the Research Program will be successful in whole or in part or result in the registration or commercialization of any pharmaceutical products or that any Products receiving regulatory approval will be a commercial success" and that the projected milestones, costs, and NDA filing dates in the ARP "do not constitute any warranty as to the future performance of the Program Compounds and that actual results may vary from such projections."

In addition, to the extent Hancock is alleging that Abbott made material misrepresentations or omissions in draft versions of the Descriptive Memoranda or ARPs, or in other written or oral statements during negotiation of the Agreement, the parties expressly agreed that such statements were disclaimed and not covered by the representations and warranties provision, therefore, they cannot form the basis for a claim. Section 12.5 of the RFA, which is set forth in capital letters for emphasis, provides that

> EACH PARTY TO THIS AGREEMENT AGREES THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS AGREEMENT. NEITHER PARTY MAKES ANY OTHER REPRESENTATIONS OR WARRANTIES, AND EACH HEREBY DISCLAIMS ANY OTHER REPRESENTATIONS OR WARRANTIES MADE BY ITSELF OR ANY OF ITS OFFICERS, DIRECTORS, EMPLOYEES, AGENTS, FINANCIAL AND LEGAL ADVISORS OR OTHER REPRESENTATIVES, WITH RESPECT TO THE EXECUTION AND DELIVER OF THIS AGREEMENT, NOTWITHSTANDING THE DELIVERY OR DISCLOSURE TO THE OTHER OR THE OTHER'S REPRESENTATIVES OF ANY DOCUMENTATION OR OTHER INFORMATION WITH RESPECT TO ANY ONE OR MORE OF THE FOLLOWING.

33. No proposed additional or substitute findings.

- 34. <u>Proposed Additional Findings</u>: During negotiations of the RFA, Abbott promptly notified Hancock of the potential problems observed in clinical trials of ABT-980 and Abbott's decision to terminate development of that compound.
 - 35. No proposed additional or substitute findings.
- 36. <u>Proposed Substitute Findings</u>: *Hancock's original proposal for* restructuring the deal was less favorable to Abbott but the parties continued to negotiate and executed the RFA as it was originally structured.
- 37. <u>Proposed Substitute Findings</u>: Despite the fact that ABT-980, a late stage compound that accounted for a significant percentage of Hancock's potential investment, had been discontinued, Abbott and Hancock moved forward with the deal in early 2001 as it was originally structured, and agreed to include ABT-492 and ABT-510 as replacement compounds for ABT-980.
- 38. <u>Proposed Substitute Findings</u>: Both parties agreed to the revised basket of Program Compounds and deal structure.
- 39. <u>Proposed Substitute Findings</u>: Abbott and Hancock, which were each represented by counsel, continued to modify and refine the terms of the proposed RFA in various ways in 2001, but the group of nine Program Compounds was not changed after the new drug compounds, ABT-492, ABT-510 and the ED Program, were added to the deal.

Abbott's March 2001 Portfolio Review Meeting

40. <u>Proposed Substitute Findings</u>: From March 7–9, 2001, Abbott conducted an off-site Portfolio Review Meeting during which 10–45 minute presentations were

given regarding over forty Abbott compounds, including the compounds that Abbott had recently required as part of the Knoll Pharmaceutical Company ("Knoll") acquisition.

- 41. Proposed Substitute Findings: Abbott retained the consulting firm McKinsey & Company ("McKinsey") in or about January 2001 to assist in the Knoll integration. Its primary role was assisting Abbott with governance and organizational issues relating to the integration of Abbott and Knoll after Abbott's recent acquisition of Knoll. The McKinsey consultants were not familiar with the Abbott compounds and, to the extent they had involvement with research and development issues, were more focused on the recently acquired Knoll assets.
- 42. <u>Proposed Substitute Findings</u>: McKinsey's duties and responsibilities included attendance at the Portfolio Review Meeting. McKinsey was not tasked with memorializing Abbott's meetings and discussions.
- 43. <u>Proposed Substitute Findings</u>: Jessica Hopfield is one of the lead McKinsey consultants who attended the Portfolio Review Meeting.
- 44. <u>Proposed Substitute Findings</u>: *In 2000-01, Dr. Hopfield was a member of McKinsey's pharmaceuticals and medical products practice.*
- 45. <u>Proposed Substitute Findings</u>: McKinsey participated in the Portfolio Review Meeting as part of its general role assisting in the integration of the Knoll assets. The purpose of the Portfolio Review Meeting was to review the development status of Abbott's entire portfolio of pharmaceutical compounds.
 - 46. No proposed additional or substitute findings.
- 47. <u>Proposed Substitute Findings</u>: McKinsey created the document entitled the "Initial Portfolio Prioritization" without direction from or consultation with Abbott.

Abbott did not task McKinsey with memorializing the Portfolio Review Meeting, or request that it do so.

- 48. <u>Proposed Substitute Findings</u>: The Initial Portfolio Prioritization document was provided to Dr. Leiden via electronic mail from Dr. Hopfield on March 13, 2001. No Abbott employee reviewed the document before it was provided to Dr. Leiden. Dr. Leiden did not review the document, nor was it forwarded to any other Abbott employees.
- 49. <u>Proposed Additional Findings</u>: Since Dr. Leiden did not review the Initial Portfolio Prioritization document or forward it to any other Abbott employees, no one from Abbott commented to McKinsey regarding the inaccuracies it contained. *The document is at a high level of generality and every Abbott witness who attended the meeting and was shown the document testified that they he never seen it before and that it is inaccurate in a number of respects.*

The Final Agreement

- 50. No proposed additional or substitute findings.
- 51. No proposed additional or substitute findings.
- 52. Proposed Substitute Findings: Even if Hancock revises its *projected* financial return based on the failure of some compounds, there is not necessarily an impact on its *actual* financial return. Hancock's *actual* financial return is dependent on various factors over the course of a multiple year contract, which cannot be predicted with certainty. In addition, the RFA is structured to reduce Hancock's risk of loss even if some of the Program Compounds fail. For example, if Abbott reduces its budgeted spending below certain levels (e.g., because of the termination of one or more

compounds), Hancock is allowed to terminate its Program Payments. After Abbott terminated certain compounds, including ABT-518, ABT-594, and ABT-773, Hancock exercised that right and was excused from \$110 million in Program Payments.

- 53. <u>Proposed Additional Findings</u>: At the time it entered into the RFA, Hancock was aware that the projected launch dates for many of the Program Compounds were many years in the future.
 - 54. No proposed additional or substitute findings.
- 55. <u>Proposed Substitute Findings</u>: Mr. Deemer subsequently sent an e-mail dated March 12, 2001 to Mr. Blewitt in which he stated:

John Leonard looked at all of the documents one last time in preparation for execution and noted an oversight on one of the Programs. On the ABT-518 program, he noted that Phase I was to have started on December 2000 (4Q2000) but in fact did not start until earlier this month. This pushed the timeline back by a quarter throughout but the launch date is not affected and is actually planned one quarter earlier (2Q06). Steve, as you know the timing of starting some of these earlier compound studies is related to completing this financing and hence the reason this one got pushed back a little.

- 56. <u>Proposed Substitute Findings</u>: *See supra*, ¶ 55.
- 57. Proposed Substitute Findings: After February 2001, Abbott revised the ABT-518 Descriptive Memoranda to reflect a delay in start of Phase I trial from 4Q2000 to IQ 2001. Thereafter, Abbott did not otherwise revise the February 15, 2001 versions of the Descriptive Memoranda before the RFA was executed by the parties on March 13, 2001. The representations made by Abbott in the RFA regarding the Program Compounds were accurate and complete in all material respects as of the date of the Agreement.

- 58. <u>Proposed Substitute Findings</u>: No compound was essential to Hancock's decision to enter into the RFA and the portfolio often changed during negotiations.
- 59. Proposed Substitute Findings: The final Descriptive Memoranda were attached to, and incorporated in, the RFA as collective Exhibit 12.2(i) and were defined as "Compound Reports." The RFA does not specify any particular content for the Descriptive Memoranda. The RFA simply defines the "Compound Reports" as "the compound reports attached as Exhibit 12.2 hereto." Abbott's first "Annual Research Plan" also is attached to, and incorporated in, the RFA as Exhibit 1.6. The RFA provides that the ARP sets forth "a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for every Program Year[.]" It also states that the Annual Research Plan provides
 - a description of projected milestones and dates thereof, projected year of NDA filing, and projected costs to be incurred by Abbott during the Program Term, for each Program Compound. Such projections were prepared in good faith and with due care based on reasonable assumptions, and represent the reasonable estimate of Abbott based on information available as of the date of such projections and as of the date hereof; it being agreed that such projections do not constitute a warranty as to the future performance of the Program Compounds and that actual results may vary from such projections.
- 60. Proposed Additional Findings: Hancock expressly agreed in Section 12.5 of the RFA that Abbott's representations and warranties were limited to statements within the written agreement itself (including the final Descriptive Memoranda and ARPs) and excluded any other representations. Thus, the representations and warranties exclude draft Descriptive Memoranda, draft ARPs, any other written documents not included in the RFA, and any oral statements. In addition, the representations and warranties concern disclosure of "material fact[s]," not opinions or immaterial facts. Abbott represented that

it had not omitted any "material fact necessary to make the statements contained herein or therein not misleading." Abbott did not represent that it had included all facts that *might* have a material adverse effect on the prospects or condition of the compounds, but rather that it had included any fact that "has resulted in, or could reasonably be expected to result in, a material adverse effect." The representations and warranties provision of the RFA also expressly provide that Abbott is not required to disclose "generally available information concerning the pharmaceutical industry in general." Finally, the parties also agreed that:

[n]otwithstanding anything in this Agreement to the contrary, Abbott does not represent, warrant or guarantee that the Research Program will be successful in whole or in part or result in the registration or commercialization of any pharmaceutical products or that any Products obtaining Regulatory Approval will be a commercial success.

- 61. No proposed additional or substitute facts.
- 62. Proposed Substitute Findings: Hancock did not actually and justifiably rely upon the representations it now alleges were misleading in deciding to enter into the Agreement on March 13, 2001 on the terms stated. Based on Abbott's disclosures and its own due diligence, Hancock was aware of the material risks of the compounds. Mr. Blewitt generally used publicly available information, not information provided by Abbott, to calculate Hancock's expected returns on the deal. Mr. Blewitt did not provide copies of the Descriptive Memoranda or ARPs to Mr. Hartz or the Hancock investment committees. Abbott and Hancock expressly agreed that the representations and warranties only applied to the final Descriptive Memoranda and ARPs, not prior drafts. Although Abbott made new disclosures to Hancock in the November 2000 and final drafts of the Descriptive Memoranda, and in the ARPs (such as the "Low" probability of "law").

nausea/vomiting" for ABT-594, the nausea and voting rates from prior clinical trials, the lack of funding for ABT-773 pediatric program, and the possibility of twice-a-day dosing for ABT-773 for more severe indications), Hancock did not take any discernable action, such as returning to the investment committee or sharing the information with Dr. Klotz.

63. <u>Proposed Substitute Findings</u> The representations made by Abbott in Sections 12.2(i) and 12.2(m) were materially accurate and complete and the alleged misrepresentations and omissions were not material to Hancock's decision to enter into the RFA on March 13, 2001 on the terms stated.

The Representations Made by Abbott in the RFA Regarding the Status and Prospects of the Program Compounds Were Accurate and Complete In All Material Respects

- 64. <u>Proposed Substitute Findings</u>: As of March 13, 2001, the status and prospects of ABT-518, ABT-594, and ABT-773, were the same, in all material respects, as represented by Abbott to Hancock in the RFA.
- 65. <u>Proposed Substitute Findings</u>: As of March 13, 2001, Abbott's plans for ABT-518, ABT-594, and ABT-773, were the same, in all material respects, as represented by Abbott to Hancock in the RFA.

ABT-518

- 66. <u>Proposed Substitute Findings</u>: ABT-518 is a pharmaceutical compound that was under development at Abbott Laboratories in 2000 and 2001. It is in a class of compounds called Matrix Metalloproteinase Inhibitors ("MMPIs") that are intended to inhibit the growth of cancerous tumors. Through 2000, Abbott had spent \$40 million developing ABT-518.
 - 67. No proposed additional or substitute findings.

68. Proposed Additional Findings: In the Descriptive Memorandum, Abbott disclosed problems experienced by competitor MMPIs, including that (1) Marimastat had shown "no survival advantage [in pancreatic cancer]" and that other MMPI compounds had not demonstrated efficacy; (2) the competitor compounds, including Marimastat and Prinomastat, had "dose limiting toxicity" that "almost certainly preclude their long-term use, limit compliance and reduce optimal efficacy"; and (3) "Bayer recently dropped development" of its MMPI compound due to concerns about potential toxicity. In addition, Abbott disclosed that because ABT-518 was at a less advanced stage of development the "[side effect] hurdles will be even higher for this compound."

Based on review of the draft Descriptive Memoranda and its own due diligence, Hancock was aware of the material risks associated with ABT-518. For example, Dr. Klotz informed Mr. Blewitt that since the use of cytostatic cancer agents, such as ABT-518 and other MMPIs, is "a new untried strategy for everyone, it is high risk. The risk is compounded by the fact that most are in discovery, not in clinical trials." Dr. Klotz told Mr. Blewitt, based on the results of his literature search, that MMPI compounds "are particularly worrisome." Based on Abbott's disclosures and its own due diligence, Hancock knew that competitor compounds had "underwhelming efficacy," and were "toxic" and caused "joint problems." Hancock's scientific expert also advised Hancock that cytostatic agents such as ABT-518 may only be useful as a combination therapy and "may not be exceptional compounds by themselves."

69. <u>Proposed Substitute Findings</u>: The Descriptive Memorandum for ABT-518 disclosed that "[c]ompanies with compounds in advanced clinical development for the treatment of cancer include" Agouron/Warner Lambert/Pfizer (developing

Prinomastat), British Biotechnology/Schering Plough (developing Marimastat), and BMS (developing BMS 275291).

70. <u>Proposed Additional Findings</u>: Each version of the Descriptive Memoranda also disclosed to Hancock that:

As the 3rd or 4th MMPI to market, Abbott's compound will need to demonstrate a meaningful clinical advantage over compounds that are in more advanced development. Strict Go/No Go criteria will determine if the MMPI can meet these hurdles. If they cannot be met, the compound will not move forward.

- 71. Proposed Substitute Findings. As of March 13, 2001, Abbott regarded ABT-518 as a "compelling development candidate" that had the potential to be "best in class" among a "novel therapeutic class" of similar compounds being developed by a range of pharmaceutical companies. As of the date of the Agreement -- based on all information available to it at the time, including the allegedly undisclosed material adverse information -- Abbott estimated ABT-518 had a 13% probability of success and worldwide peak sales of \$496 million, both higher than Hancock's estimates.
- 72. <u>Proposed Substitute Findings</u>. The representations made by Abbott in the RFA regarding the prospects and condition of ABT-518 as of the date of the Agreement were accurate and complete in all material respects.
- (a) <u>Proposed Substitute Findings</u>: On August 7, 2000, Pfizer *publicly* announced that "preliminary results of Phase III clinical trials of prinomastat . . . in advanced hormone refractory prostate cancer and advanced (stage IV) non-small cell lung cancer did not meet primary efficacy objections" and that "Pfizer is halting these two Phase III trials," but that "the company intends to continue exploration of prinomastat in other tumor types and most importantly, in earlier stage disease, where oncologists believe inhibition of angiogenesis may have greater utility." Pfizer reported

that "four Phase II trials are currently underway and two additional Phase II trials will begin shortly." In February 2001, it was publicly reported that British Biotech, based on results from a Phase III trial of Marimastat in patients with single cell lung cancer, had decided that it will not to file for approval of marimastat, although ongoing Phase III trials will continue. Subsequently, in May 2001, British Biotech reported that "the future direction of Marimastat development is "the subject of ongoing discussion with Shearing-Plough and with external experts." As of the date of the RFA, these companies had not released clinical data from these trials and Abbott's knowledge regarding the status of their programs was limited to the information that had been publicly reported.

(b) Proposed Substitute Findings: From March 7–9, 2001, Abbott's senior management held a Portfolio Review Meeting for the purpose of examining the "technical, scientific, medical and commercial" status of compounds under development. Dr. Perry Nisen, the head of Abbott's oncology program, gave a presentation regarding ABT-518. As reflected in the presentation, Abbott believed ABT-518 had potential advantages over competitor MMPI compounds, such as greater selectivity in targeting enzymes, greater potency, and lack of joint pain side effects. As disclosed to Hancock, however, it was not yet known whether ABT-518 would be able to demonstrate advantages over the competitor MMPI compounds. Abbott believed its MMPI compound was more potent and more selective than the competitor compounds, and hoped to be able to avoid the problems faced by competitors. If problems experienced by competitor compounds were unique to those compounds and were not classwide effects, Abbott would have a competitive advantage. Abbott could not draw conclusions regarding the significance of the publicly available information regarding competitor

compounds until it had the scientific data regarding the competitor's recent clinical trials, which were to be disclosed at a conference of the American Society of Clinical Oncologists ("ASCO") scheduled for May 12–15, 2001.

(c) <u>Proposed Substitute Findings</u>: After the Portfolio Review Meeting,

Abbott's senior management, led by Dr. Leiden, initially decided to put a temporary hold on the enrollment of patients in the Phase I clinical trial of ABT-518 while awaiting the release of clinical data regarding competitor MMPI compounds at the ASCO meeting in mid-May. Dr. Leiden's initial decision to place a temporary hold on ABT-518 was based upon limited information—a 15 minute presentation at the Portfolio Review Meeting.

Others at the meeting, including Dr. Leonard and Dr. Nisen, who were more familiar with the compound than Dr. Leiden, disagreed with the decision. Dr. Azmi Nabulsi, the medical director for the ABT-518 program, also disagreed with the decision.

The Initial Portfolio Prioritization document prepared by McKinsey is inconsistent in its purported description of discussions at the Portfolio Review Meeting regarding ABT-518. While one version states "Hold/[T]erminate," other versions simply state "Hold." Ms. Hopfield could not explain the discrepancy and Abbott personnel who attended the meeting testified that there was no decision at the meeting to terminate ABT-518, but rather to place a hold on the program while awaiting results from ASCO. Irrespective of the inconsistent terminology used in different versions of the Initial Portfolio Prioritization document, all versions indicate that Abbott would not make any decision regarding continued development of the program until after the ASCO conference. All versions of the document state that Abbott will "[w]ait for May results from Pfizer" at the ASCO conference in order to "save ~ \$1 mill" in clinical trial costs,

and that senior management will "re-evaluate" the program after the ASCO conference in "May."

Ms. Hopfield did not recall any discussions regarding halting or "stopping development" of ABT-518. Ms. Hopfield testified that "'Hold' meant "do not spend any incremental funds if not required until a decision was made" and that "halt all further expenditure" meant "any optional clinical or commercial spend should be stopped until it was clear what was going to happen to the compound." She confirmed that the majority of the attendees at the meeting, including the executive group, were in favor of either deferring a decision regarding ABT-518 until after results regarding competitor MMPI compounds were released at ASCO in May or supporting continuation irrespective of the ASCO results.

- (d) Proposed Substitute Findings: After Dr. Leiden's initial decision to place a hold on the clinical trial pending release of data at ASCO, doctors in the Netherlands were instructed to defer enrollment of any additional patients in the Phase I clinical trial. On March 12, 2001, Abbott told the investigators to continue the study with the one patient who had enrolled and await "further instructions by tomorrow." The next day, Abbott lifted the hold.
 - (e) <u>Proposed Substitute Findings</u>: *Supra*, ¶ (d).
- (f) <u>Proposed Substitute Findings</u>: Dr. Leiden lifted the hold on the development of ABT-518 because Dr. Leonard and Dr. Nisen convinced him that Abbott would not save a lot of money by putting ABT-518 on hold and leaving the study running would save time after the release of ASCO data in May. *Dr. Leonard also noted that* "we ha[ve] a partner [Hancock] in this program and this [is] part of our general risk

mitigation strategy of risk sharing and that we should proceed." Even if Dr. Leiden had taken this fact into consideration in restarting the trial, that would not have been surprising to Hancock since it knew that the RFA was intended to allow Abbott to develop more compounds than it would if limited to its own internal budget.

- (g) <u>Proposed Substitute Findings</u>: On March 13, 2001, the one-day hold on the clinical trial for ABT-518 was lifted based on the scientific and commercial considerations noted above. The temporary hold had no material impact on Abbott's development of ABT-518. On March 13, 2001, Abbott and Hancock also executed the RFA.
- 73. <u>Proposed Substitute Findings</u>: On March 13, 2001, Abbott directed doctors in the Netherlands to continue with the clinical trial as planned. The next patient in the clinical trial was enrolled on March 26, 2001.
- 74. Proposed Substitute Findings: Other development work, including analysis of preclinical toxicology results, continued to be performed after the hold on the clinical trial had been lifted. Since the Phase I clinical trial was the most important development activity for ABT-518 as of March 2001, it was immaterial to the critical path for the development of the compound whether or not certain other, less important activities remained on hold pending the ASCO conference.
 - 75. <u>Proposed Substitute Findings</u>: *Infra*, ¶¶ 76-81.
- 76. <u>Proposed Substitute Findings</u>: On May 12–15, 2001, members of the ABT-518 team attended the ASCO conference. At the conference, detailed scientific information regarding the clinical trials of other MMPI compounds was presented by scientists in the form of oral presentations, abstracts, and other documents. On or around

May 28, 2001, after the ASCO conference, Dr. Nisen made a presentation to senior management summarizing the MMPI competitor data presented at ASCO and the progress of the Phase I clinical trial to date. Based on the ASCO data, Abbott senior management decided to discontinue funding for ABT-518 and terminate internal development of the compound. At that point, Abbott generally ended enrollment of patients in the Phase I clinical trial. Patients already enrolled in the trial were allowed to continue until reaching the clinical endpoint.

- 77. <u>Proposed Substitute Findings</u>: *Supra*, ¶ 76.
- 78. Proposed Substitute Findings: Abbott did not make a decision to terminate development of ABT-518 at its May 2001 Strategy Retreat. The purpose of the Strategy Retreat was to discuss strategies regarding therapeutic areas, not prioritization or decision-making regarding development of particular compounds. A McKinsey document titled "Strategy Retreat Output" includes a one-word reference to "Terminate" but Ms. Hopfield testified that there was no decision to terminate ABT-518 at the May Strategy Retreat and that she could not explain the meaning of the reference. The document also contained other inaccuracies. All of the Abbott documents reflect a consistent plan to make a decision based on the ASCO data to be released in mid-May.
- 79. Proposed Substitute Findings: ASCO rules provide that presentations at the conference cannot include previously released data, therefore, by necessity all the clinical data released at ASCO was new. Abbott learned for the first time at the ASCO conference the scientific data regarding lack of efficacy and side effects in recent clinical trials of competitors' MMPI compounds. Some members of the ABT-518, including Dr. Nabulsi and Dr. Nisen, acting as "advocates for a program they had been working on for

many years", supported continuing clinical trials of ABT-518 notwithstanding the data released at ASCO, but Dr. Leonard and Dr. Leiden concluded based on that data that the chances of success for ABT-518 were too low to justify continued development.

- 80. <u>Proposed Substitute Findings</u>: Dr. Leiden's decision to terminate ABT-518 was conveyed to Abbott employees working on ABT-518 in early June 2001, and to the investigators conducting the trial in mid-June 2001.
- 81. Proposed Substitute Findings: Abbott concluded the ABT-518 clinical trial with the patients enrolled to date and conducted analyses of data from the trial. In Fall 2001, Dr. Nisen presented senior management with a detailed analysis of the data from the clinical trial of ABT-518 and data from ASCO. Abbott management concluded that, although there was still some possibility that ABT-518 could avoid the problems experienced by competitor MMPI compounds, the negative data released at ASCO made continued development too high risk to warrant continued internal funding. In Fall 2001, Abbott made presentations to the National Cancer Institute ("NCI") and the Goodwin Foundation regarding potential collaborative efforts to continue development of ABT-518, but the institutions declined.
- 82. <u>Proposed Substitute Findings</u>: On September 20, 2001, in accordance with the RFA, Abbott notified Hancock that it had discontinued its development of ABT-518.
- 83. <u>Proposed Additional Findings</u>: The RFA did not require Abbott to explain the reason for its decision to terminate ABT-518.

- Proposed Substitute Findings: Abbott did not believe that the temporary 84. hold on ABT-518 in March 2001 was material or that knowledge of the hold would impact Hancock's willingness to enter into the deal.
- 85. Proposed Substitute Findings: Abbott's management personnel did not believe that a slow down in the development of ABT-518 had the potential to impact the structure of the RFA. The comments expressed by Mr. Deemer in his March 20, 2001 email to Dr. Nisen were an exaggeration for effect of his actual belief, which was that a slow down of ABT-518 would have delayed finalization of the deal but would not have ultimately prevented finalization of the deal. For example, Abbott's disclosure—in an email to Hancock the day before the RFA was executed—that the beginning of Phase I for ABT-518 had been delayed for three months (from 4Q2000 to 1Q2001) had no impact on Hancock's willingness to enter into the RFA. Abbott's disclosure in Fall 2000 that it had terminated the Phase III compound ABT-980 did not prevent the parties from reaching agreement, and ABT-518 was a minor component of the deal compared to ABT-980.
- 86. Proposed Substitute Findings: In an email after the Agreement was signed, Mr. Deemer expressed an opinion that the Agreement could have been impacted if, in fact, ABT-518 was being "slowed down," but he then observed in the same email that ABT-518 is "back on track." That observation is consistent with the evidence that shows that the hold on ABT-518 lasted only a day and had no material impact on the development of ABT-518.

- 87. <u>Proposed Substitute Findings</u>: Abbott disclosed all material information regarding the prospects and condition of ABT-518 as of March 13, 2001 to Hancock before Hancock entered into the RFA.
- 88. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent or fail to disclose any material information concerning the prospects and condition of ABT-518 to Hancock in the Agreement.
- 89. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent or fail to disclose any material information concerning the prospects and condition of ABT-518 to Hancock in the Agreement. Abbott did not engage in any fraudulent or wrongful conduct or act with any fraudulent or wrongful intent.
- 90. <u>Proposed Substitute Findings</u>: Disclosure of the temporary hold, the reasons for the hold, and/or the resumption of the clinical trial of ABT-518 to Hancock before execution of the RFA would not have "significantly altered the economics and attractiveness of the proposed funding deal."

ABT-518 represented only \$1 million of Hancock's \$214 million investment. Hancock estimated that ABT-518 had only a 10 percent chance of success and that, even if successful, the royalties would be far in the future. Thus, even the complete elimination of that compound from the Agreement would not have significantly impacted the overall financial attractiveness of the deal.

91. <u>Proposed Substitute Findings</u>: Hancock has not suffered monetary or other damages due to any alleged misrepresentations, omissions or fraud with regard to ABT-518.

ABT-594

- 92. <u>Proposed Substitute Findings</u>: ABT-594 is a pharmaceutical compound that was under development at Abbott Laboratories from 1997 through 2001. ABT-594 is a cholergenic channel modulator ("CCM") or neuronal nicotinic receptor agent ("NNR"). Through 2000, Abbott had spent \$97.3 million developing ABT-594.
 - 93. No proposed additional or substitute findings.
 - 94. No proposed additional or substitute findings.
- 95. Proposed Additional Findings: In the November 2000 and the final version of the Descriptive Memorandum, Abbott noted that the likelihood of ABT-594 reaching its target profile of low nausea/vomiting was "Low." Abbott also disclosed that during previous clinical trials, the "most common adverse events for subjects receiving 75 μg [micrograms] BID [twice-a-day] were nausea (15%), headache (13%), dizziness (7%), insomnia (6%), and vomiting (5%)." Abbott disclosed that the therapeutic window (i.e., the ratio between the maximum tolerated dose and the minimum efficacious dose) might be small. The Descriptive Memoranda state that the Phase IIa studies "suggest a trend towards analgesic effect [efficacy]" at 75 micrograms twice-a-day and that Phase I studies indicated that the maximum tolerated dose might be as low as 150 micrograms per day. Abbott further disclosed in the RFA that a "Go/No Go" decision for clinical efficacy was expected in June 2001 at the conclusion of the Phase IIb (dose-ranging) trial ("M99-114").
- 96. <u>Proposed Additional Findings</u>: Abbott disclosed to Hancock in the RFA that there was a "Go/No Go" decision scheduled for ABT-594 in June 2001. Abbott estimated that it would spend \$9.3 million on ABT-594 through its "Go/No Go" decision

in June 2001, and an additional \$5.6 million on ABT-594 after June 2001, provided there was a "Go" decision. The post-June spending was part of Abbott's "blue plan." Abbott often allocated "blue plan" spending contingent on events such as "Go/No Go" Decisions.

97. Proposed Substitute Findings: Hancock did not show Dr. Klotz the November 2000 draft of the Descriptive Memorandum or the final Descriptive Memorandum, which contained the disclosure by Abbott that the likelihood of ABT-594 reaching its target profile of low nausea/vomiting was "Low." Dr. Klotz testified that if he had seen those drafts, that disclosure would have raised "a huge red flag" for him.

Even based on the April 2000 draft of the Descriptive Memorandum, however, Dr. Klotz recognized that (1) there "may be a problem with the therapeutic window;" (2) "10% of patients at 75 µg (micrograms) BID [twice-a-day dosing] had a number of uncomfortable side effects such as headaches, nausea, etc;" and (3) the therapeutic window of ABT-594 could be too narrow and that there was "some risk of not passing phase II clinical trials." The disclosures made by Abbott in the April 2000 draft ABT-594 Descriptive Memorandum regarding adverse events and the therapeutic window of ABT-594 raised a "red flag" for Dr. Klotz. Based on Abbott's disclosures, Dr. Klotz recommended that Hancock seek the opinion of a pain clinical trials expert and told Hancock that it was "important that we see a summary of the latest clinical trial data." Although Abbott had offered, and stood ready, to provide Hancock with access to whatever additional data it requested, Hancock did not request any additional data because, according to Dr. Klotz, Mr. Blewitt did not think it was necessary. Although Hancock never requested additional ABT-594 clinical study data, Abbott nonetheless

28 4881848 1

Case 1:05-cv-11150-DPW

provided such data, including nausea and vomiting rates from completed trials, in subsequent drafts and the final ABT-594 Descriptive Memorandum that were provided to Hancock. Dr. Klotz interviewed a clinical trials pain expert, Mitchell Max, M.D., regarding ABT-594. Dr. Max stated that, in his opinion, a "therapeutic window of two [the low end of the range identified by Abbott of two to three] is certainly acceptable." Based on Dr. Max's opinion and its other due diligence, Hancock was satisfied that the level of risk regarding ABT-594 was acceptable and approved the deal. The September 21, 2000 Purchase Recommendation stated "Our scientific consultant, Dr. Mitchell Max, NIH, eliminated an initial concern of ours that the 'therapeutic window' of ABT-594 was too short and would potentially block approval." Hancock alleges that disclosures by Abbott regarding the clinical trial and drop-out rates would have revealed issues regarding nausea and vomiting and thereby changed the attractiveness of the deal. But when Abbott provided Hancock with an updated Descriptive Memorandum in November 2000 that disclosed a "Low" probability of "low nausea/vomiting" and made other disclosures regarding nausea and vomiting, Mr. Blewitt did not bring these disclosures to the attention of the Hancock investment committees, consult with Dr. Klotz, request additional information from Abbott, or take any action whatsoever.

- 98. <u>Proposed Substitute Findings</u>: The representations made by Abbott in the RFA regarding the prospects and condition and anticipated spending for ABT-594, as of the date of the Agreement, were accurate and complete in all material respects.
- (a) <u>Proposed Substitute Findings</u>: Abbott's Phase IIb trial of ABT-594 for the treatment of diabetic neuropathic pain (known as trial "M99-114") commenced in April 2000. The trial was initially designed to include 320 "subjects" or patients in a "double-

Case 1:05-cv-11150-DPW

blinded" format. In such studies the investigating physician does not know whether he or she is administering an investigational drug as opposed to a placebo to any particular patient, and the patient and the investigating physician do not know what dose the patient is receiving. The sponsor of the trial (i.e., Abbott) also does not know this information. In order to have a successful trial, Abbott needed to enroll sufficient patients to achieve a statistically significant result, i.e., one that would allow Abbott to determine whether there was a clinically meaningful difference between each of the three doses of ABT-594 and the placebo.

M99-114 was a dose ranging study to determine the doses at which ABT-594 would be efficacious and well tolerated. Therefore, the trial included patients in four different dose groups: placebo, 150 mcg, 225 mcg, and 300 mcg BID (twice-a-day). M99-114 was designed to determine a dose at which patients would experience the efficacy of the drug without adverse side effects. Abbott thus expected that at the higher doses there would be drop-outs from side effects; those doses had been selected specifically to define an adverse event profile. Abbott did not have any material concerns that the drop-out rate for M99-114 would result in an unsuccessful result before the trial was unblinded in April 2001.

Dr. Leonard's statement to Mr. Blewitt and Dr. Klotz in a July 2000 conference call with Dr. Klotz and Mr. Blewitt that the side effects of from ABT-594 "aren't dangerous: headache and vomiting" and that "[t]hese minor side effects appear to go away over time" accurately reflected Abbott's knowledge regarding the compound, as evidenced by its own documents. For example, Abbott's February 8, 2001 protocol for the M99-114 study reported that adverse events in previous trials "were considered to be

mild in the opinion of the investigator", "subjects generally tolerated ABT-594 better . . . after 3-4 days of repeated dosing (the period in which most adverse events occur)" in Phase I trials, and "ABT-594 appeared to be tolerated better after the first week of therapy" in Phase II trials. Similarly, after the conclusion of the M99-114 trial, Abbott's clinical study report noted that, in that trial, "[m]ost adverse events were mild or moderate in severity."

(b) Proposed Substitute Findings: It is not uncommon for clinical trials to experience challenges in reaching target enrollment on schedule. Abbott's challenges in reaching the original target enrollment for the M99-114 study were due, in large part, to factors unrelated to adverse events or patient drop-outs, such as the relatively limited numbers of diagnosed diabetic neuropathy patients, the stringent screening criteria, and the reluctance of candidates suffering from pain to forgo other pain medication and enroll in a placebo-controlled study.

Hancock's statement that, as of July 7, 2000, 31 of the 78 patients enrolled in M99-114 had pre-terminated because of "adverse events" is not supported by the document Hancock relies on, which shows 20 of the 78 patients (26%) had pre-terminated due to adverse events and does not identify whether the other eleven patients pre-terminated due to reasons other than adverse events. As discussed below, M99-114 was adequately powered to achieve its clinical objectives despite the drop-out rate.

(c) <u>Proposed Substitute Findings</u>: Since M99-114 was a double-blinded, dose-ranging study, Abbott could not determine at what doses the adverse events or dropouts were occurring until completion of the trial in April 2001. It was possible, for example, that the adverse side effects were occurring at the higher doses and the lowest

dose of 150 mcg would be both efficacious and well tolerated. Also, Abbott expected that, as in any study, patients would pre-terminate for reasons unrelated to adverse events, including lack of efficacy. Drop-outs among the 25 percent of patients receiving a placebo were especially likely in this study because the patients were suffering from diabetic neuropathic pain, and under the protocol were not allowed to be on any other pain medicine.

- (d) <u>Proposed Substitute Findings</u>: Abbott requested that the M99-114 clinical test sites provide information regarding the types of adverse events patients were experiencing, but this was not unusual or indicative of a problem with the trial. Also, because the trial was double blinded, the surveys did not provide Abbott with any data regarding the doses at which patients were experiencing adverse events.
- (e) <u>Proposed Substitute Findings</u>: Abbott's senior management regarded compounds in Phase II that did not have statistically significant clinical trial results as having questionable commercial viability because the likelihood of success of such a compound was lower than compounds that were in more advanced stages of development.
- (f) Proposed Substitute Findings: Abbott employees received limited blinded information regarding side effects patients on the drug were experiencing. Abbott had observed that side effects of nausea and vomiting were dose-related in earlier clinical studies of ABT-594. The fact that the side effects were dose-related was one of the reasons Abbott could not determine, until after the results of the M99-114 trial were unblinded, whether there was an efficacious dose at which the side effect profile was acceptable.

- Proposed Substitute Findings: In December 2000 Abbott decided not to (g) retain a patient recruitment firm for the M99-114 clinical trial because it had determined that it could enroll sufficient patients to have a successful trial.
- (h) Proposed Substitute Findings: In December 2000, Abbott's statisticians determined that enrolling a smaller number of patients than the original target of 320 would still yield a statistically significant result, and thus accomplish the purposes of the study. The phrase "prematurely terminated" that is used in Abbott documents simply means that enrollment ended with less patients than originally planned, and does not mean that the study was not conducted to its planned conclusion. Abbott determined that this decision was advantageous for the development of ABT-594, because it would allow Abbott to complete its study by April 2001, as planned, and, if the results were positive, maintain its planned timetable for further studies and potential launch in 2003. As predicted by Abbott's statisticians, reducing the number of patients in the M99-114 trial did not have any significant impact on the ability of Abbott to have a successful clinical trial. Closing enrollment early only reduced the power of the study by 6 percent, a reduction that was neither meaningful nor significant. Prior Phase II clinical trials for ABT-594 utilized planned power of less than 80%.
- Proposed Substitute Findings: Abbott stopped enrollment of patients in its (i) Phase IIb study on January 5, 2001 at 269 subjects, and continued the study to completion.
- Proposed Substitute Findings: The drop-out rate experienced in the M99-(j) 114 trial was not unusual for a clinical trial of pain-related compounds and would not have been a concern for Abbott unless it prevented Abbott from adequately powering the

Page 34 of 103

clinical trial, which it did not. The only "concerns" expressed by some Abbott personnel in July and August 2000 relate to the potential impact of patient drop-outs on the enrollment "goal" of 320 patients, not the ultimate results of the study. By December 2000, any such concerns regarding enrollment were moot because Abbott had enrolled a sufficient number of patients to have an adequately powered, statistically valid study.

No valid predictions or conclusions can be based on the number of adverse events experienced in a double-blinded clinical trial until the data is unblinded. Abbott did not make any such predictions or draw any such conclusions from the blinded M99-114 data. Abbott is ethically obligated to check the blinded data to make sure there are no serious adverse events.

Abbott's development of other NNR compounds concurrently with ABT-594 did not reflect a lack of confidence in ABT-594.

- Proposed Substitute Findings: Abbott often discussed ending enrollment (k) in clinical trials early if Abbott believed it would be able to have a successful trial in a shorter period of time. Abbott's decision to close enrollment in the M99-114 trial early was driven by (1) its desire to evaluate the outcome of the study early; (2) its realization that it would be able save a significant amount of time and money and still have a successful clinical trial; and (3) the desire to move the compound forward and begin clinical trials that were dependent on the results of the M99-114 trial, including subsequent Phase III trials, if supported by the M99-114 data.
- (1) Proposed Substitute Findings: Abbott explored a potential partnership (i.e., co-development) for ABT-594 with other pharmaceutical companies in late 2000 because it wished to share the overall cost of development of ABT-594. Neither the

enrollment decision nor Abbott's exploration of a potential co-development deal were material adverse events in the development of ABT-594.

- (m) Proposed Substitute Findings: Abbott personnel were not concerned about the potential impact of disclosing nausea and vomiting issues relating to ABT-594 to possible development partners, as evidenced by Abbott's disclosure to Hancock of the "Low" probability of achieving "low nausea/vomiting" rates and Abbott's disclosure to Purdue Pharma of the incidence rates of adverse events from prior clinical trials. Dr. McCarthy, the medical director of the ABT-594 development team, believed that the personal concerns expressed in an email to him from Robert Weiland regarding this issue were unjustified.
- (n) <u>Proposed Substitute Findings</u>: In late 2000, Abbott communicated with Purdue Pharma regarding a potential co-development deal for ABT-594. Purdue Pharma decided to defer negotiations regarding a potential deal until the Phase IIb trial was complete and the clinical data was available.
- spending on ABT-594 for 2001, it simultaneously increased its planned spending on the compound for the years 2002 through 2004. For example, the RFA states that Abbott would spend \$45 million on ABT-594 in 2002. As of March 2001, Abbott's internal estimate of its ABT-594 spending for 2002 was \$59.6 million. At the same time, Abbott's 2003 estimated spending increased from the \$32 million stated in the RFA to \$55.7 million, and its estimate for 2004 was \$21.8 million, \$6.8 million greater than stated in the RFA. Overall, for calendar years 2001 through 2005, Abbott estimated

spending \$163.6 million on ABT-594, an amount \$24.6 million more than the \$139 million Abbott had represented in the RFA that it would spend.

- (p) Proposed Substitute Findings: As reflected in a presentation to Abbott senior management on March 7–9, 2001, Abbott anticipated commencing the Phase IIb Osteoarthritis Pain study in 2001 for ABT-594. Abbott also planned to fund ABT-594 Phase II and Phase III trials in calendar years 2002 and beyond. Abbott scheduled the Phase IIb study to begin after the results from the M99-114 study were unblinded in April 2001 if a "Go" decision was reached. The minor delays in the initiation of Phase III trials cited in Abbott's March 2, 2001 reference package would not have delayed the compound's estimated NDA or launch dates. The Phase III trials were delayed only from October 2001 to April 2002 (assuming a "Go" decision after the Phase IIb trial). The reference package provided for a September 2003 New Drug Application ("NDA") filing date for ABT-594, the same NDA filing date disclosed to Hancock in the RFA. The planned start dates for the additional Phase II and III studies provided to Hancock were the same dates that Dr. McCarthy included in a presentation to Abbott senior management in March 2001.
- q) Proposed Substitute Findings: The ABT-594 development team made a project review presentation to senior management, including Dr. Leiden, on February 2, 2001. The only information concerning the M99-114 clinical trial that was presented to senior management was that the study was ongoing and included titrated doses up to 300 mcg BID and that the results of the study would be used to make a Go/No Go decision later that year. The presentation did not include information about adverse events in the M99-114 study. After the meeting, a recommendation was made for a comprehensive

strategy to address the tolerability issues that had been observed with the compound in all of its prior preclinical and clinical trials. Since Dr. Leiden was reviewing the ABT-594 project in-depth for the first time, he proposed that a strategy be developed to address the long-standing issues with the compound.

- (r) <u>Proposed Substitute Findings</u>: Abbott knew, and disclosed to Hancock, that dose-limiting adverse events of nausea, dizziness, and emesis ("vomiting") had been observed in prior clinical trials. Abbott did not know, as of February or March 2001, whether it would be able to overcome the dose-limiting side effects by finding a dose that was both efficacious and tolerable in terms of side effects, and disclosed this uncertainty.
- (s) Proposed Substitute Findings: Abbott reviewed its entire portfolio, over forty compounds, during the March 7–9, 2001 Portfolio Review Meeting. Abbott believed, as of March 2001, that ABT-594 was a promising novel pain medication with the potential to be the first compound in its class to be approved. Abbott estimated ABT-594 had a 45% probability of completing Phase II and 70% probability of completing Phase III which was consistent with CMRI industry averages for Phase II compounds of 51% and 65%, respectively, and consistent with industry averages for Phase II NSAID analgesics of 30% and 71%, respectively for an overall probability of success of 32%. At the Portfolio Review Meeting, Dr. McCarthy made a presentation regarding ABT-594 that was positive regarding the prospects of ABT-594 and supported continuation of the program. Phase IIb study adverse events and drop-outs were not discussed at the Portfolio Review Meeting.
- (t) <u>Proposed Substitute Findings</u>: Abbott's senior management did not surmise that the results of the Phase IIb trial would be negative. There was no way for

Abbott's senior management to predict that the outcome of the blinded M99-114 clinical trial would be negative, nor did it do so. Although Ms. Hopfield testified that there was a discussion of the possibility of termination at the Portfolio Review meeting, her testimony was contradicted by the attendees of the meeting, and, in any event, Ms. Hopfield testified that the discussion consisted of "guessing" and the participants in the meeting "simply did not know enough to make a decision", therefore, "the program was to continue as planned by the team" pending release of additional information. At the March 2001 meeting, participants were polled regarding their preferences as to whether to continue the development of each compound, to terminate the compound, or to defer decision.

Only 14% of the attendees were in favor of "Eliminate/Hold" with respect to ABT-594; 86% supported either continuing the program outright or deferring any decision until after release and analysis of the Phase IIb data.

Abbott's senior management to make decisions regarding the termination of a compound based on blinded data from an ongoing clinical trial. The presentation made to senior management at the March 2001 meeting noted that data from the Phase IIb trial would not be available until May 2001 and that there would be a "Go/No Go" decision in June 2001. The presentation also included the same adverse event rates from prior trials that were disclosed to Hancock in the RFA. Senior management did not believe, as of March 2001, that ABT-594 would probably be terminated. As of the time of the RFA, Abbott's estimate of the probability that ABT-594 would complete Phase II was substantially the same as the industry average for a compound in Phase II and higher than the industry average for analgesics.

- 99. Proposed Substitute Findings: After the unblinded M99-114 data became available to Abbott for the first time in April, Abbott conducted an analysis of the scientific and commercial prospects of the drug for nearly six months. *The unblinded data provided information regarding the rates of efficacy, nausea, vomiting, other AEs, and discontinuation according to dose group. Most adverse events experienced by patients during the trial were "mild or moderate in severity."* During that period, Abbott considered alternative dosing schemes and formulations that would minimize side effects, including an additional Phase I trial with a lower dose of ABT-594. Ultimately, in October 2001, Abbott decided to discontinue development of ABT-594 after concluding, based on the unblinded M99-114 data released in April 2001 and its subsequent analysis, that the therapeutic window of ABT-594 was too narrow to continue its development. Abbott's final decision was not made until October 2001, six months after the M99-114 results were unblinded.
- 100. <u>Proposed Substitute Findings</u>: Abbott informed its employees in October2001 that Abbott was discontinuing development of ABT-594. Abbott informedHancock of its decision in a letter dated November 20, 2001.
- 101. <u>Proposed Additional Findings</u>: The RFA does not contain any provisions requiring Abbott to inform Hancock of the reasons for the termination of any of the Program Compounds.
- 102. <u>Proposed Substitute Findings</u>: Abbott disclosed the true material prospects and conditions of ABT-594 as of March 13, 2001, as well as Abbott's expected spending on ABT-594.

- 103. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent or fail to disclose material information concerning the prospects and conditions of ABT-594, or its expected spending on that compound, to Hancock in the RFA.
- 104. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent or fail to disclose material information concerning the prospects and conditions of ABT-594, or its expected spending on that compound, to Hancock in the RFA. Abbott did not engage in any fraudulent or wrongful conduct or act with any fraudulent or wrongful intent.
- 105. <u>Proposed Substitute Findings</u>: The allegedly misrepresented and omitted information regarding ABT-594 was not material and would not have significantly altered the economics and attractiveness of the proposed deal from Hancock's perspective, or caused it to not enter into the agreement.
- 106. <u>Proposed Substitute Findings</u>: Hancock has not suffered monetary or other damages due to any of the alleged misrepresentations, omissions or fraud regarding ABT-594.

ABT-773

Abbott Laboratories from 1997 through 2002. ABT-773 is an anti-infective compound, in a class of antibiotics known as ketolides, which Abbott believed was promising and likely to have activity against resistant strains of bacteria and to compete effectively against marketed antibiotics. Through 2000, Abbott had spent approximately \$188.4 million developing ABT-773. As of the time of the RFA, Abbott estimated – based on all available information, including the allegedly undisclosed material adverse facts – that

ABT-773 had a 72 percent probability of technical success, slightly higher than Hancock's own estimate and consistent with industry averages for Phase III compounds.

- 108. No proposed additional or substitute findings.
- Abbott disclosed in the Descriptive Memorandum for ABT-773 that during Phase II trials conducted in 1999, 1% of patients taking both the 100 mg and 200 mg TID (three times a day) doses of ABT-773 experienced elevated liver function tests. With regard to the dosing of the compound, Abbott disclosed in the ARP that tablet dosing for ABT-773 would be "150 mg QD [once-a-day] or 150 mg BID [twice-a-day] dosing based on severity of indications." With respect to the pediatric program, the Descriptive Memorandum states that an "oral formulation" would "enabl[e] penetration" into the pediatric market but makes no representations regarding the timing of the program. Furthermore, the ARP states that the indications for ABT-773 are "Adult Tablet" and "I.V." and reflects that Abbott did not plan to spend any money on pediatric or taste testing studies for the oral formulation in 2001.
 - 110. No proposed additional or substitute findings.
- 111. <u>Proposed Substitute Findings</u>: Quinolones are a type of antibiotic with which ABT-773 would potentially compete. In the RFA, Abbott disclosed that ABT-773 would compete with quinolones and other types of antibiotics. Abbott and Hancock included ABT-492, a quinolone, as one of the Program Compounds in the RFA.
- 112. <u>Proposed Substitute Findings</u>: Abbott stated in the Descriptive Memorandum that ABF-773 "dosing is expected to be once-a-day," but disclosed in the ARP that dosing might not be once-a-day for all indications. *Mr. Blewitt testified that he*

believed that the disclosure in the ARP meant that all four indications would be approved for once-a-day dosing but in some instance patients might have to take the drug twice-a-day, but he did not offer a basis for a belief that a drug would be offered in that type of variable dosing scheme and he never consulted Dr. Klotz or Abbott regarding the meaning of the disclosure.

- 113. Proposed Substitute Findings: Abbott was developing ABT-773 for four indications: acute bacterial exacerbation of chronic bronchitis, pharyngitis, community-acquired pneumonia ("CAP"), and acute bacterial or maxillary sinusitis. The most valuable market for ABT-773 was in the two less severe indications, chronic bronchitis and pharyngitis. While it was desirable to have QD dosing for the two less severe indications, Abbott did not believe that BID dosing for the more severe indications would prove a significant commercial challenge because many of the drugs on the market for those indications were twice-a-day or three-times-a-day ("TID") and the market for those indications was smaller. Although once-a-day dosing was preferable for the US market, it was only a "minor" factor in markets outside the United States, which were expected to account for nearly half of the total sales of ABT-773.
- 114. <u>Proposed Substitute Findings</u>: The FDA's "pediatric rule" only requires a drug sponsor to initiate pediatric studies at some time prior to regulatory approval of the adult formulation, or to obtain a waiver from that requirement. The rule does not require successful development of a pediatric program to gain approval of an adult formulation.
- 115. <u>Proposed Substitute Findings</u>: The representations Abbott made in the RFA regarding prospects and condition of ABT-773, as of the date of the Agreement were accurate and complete in all material respects.

(a) <u>Proposed Substitute Findings</u>: As a result of disclosures by Abbott and information that was publicly available, Hancock was aware that some antibiotics, such as macrolides and quinolones, had abnormal heartbeat (QT prolongation) and/or liver toxicity problems. Hancock knew that ABT-773, a ketolide, was derived from macrolides and had a similar mechanism of action.

As of March 2001, Abbott did not believe ABT-773 had any QT or hepatoxicity issues that could reasonably be expected to have a material adverse effect on the ABT-773 program. Abbott's internal discussion of hepatoxicity stemmed not from any evidence of hepatoxicity with regard to ABT-773, but from the FDA's general concern with the potential for hepatoxicity of all pharmaceutical compounds absorbed by the liver, including all antibiotics. Information regarding the FDA's concern with liver toxicity issues with regard to all antibiotics was available on the FDA's website and was well known to the entire pharmaceutical community. After further testing, Abbott concluded that the elevated liver function test ("LFT") results initially observed in one Hawaiian Phase I study were caused by the high caloric diet of the particular Japanese patients in the study, and were not a side effect of ABT-773. Abbott had concluded, as of January 2001, that ABT-773 was clear in terms of hepatoxicity profile. Similarly, Abbott's internal discussion of QT issues did not reflect any concerns specific to ABT-773. It was simply a reflection of the fact that, as recognized by the pharmaceutical industry as a whole, QT prolongation was a general drug safety issue that needed to be studied in preclinical and clinical trials for antibiotics. Abbott had some data regarding QT prolongation for ABT-773, but only at doses much greater than those that would be prescribed for patients (over 800 mg). As of March 2001, there were no data indicating

that ABT-773 had QT issues at normal doses (150 mg). Even if ABT-773 had QT or liver issues, which it did not, those issues would not have precluded regulatory approval or commercial success. Many macrolide and quinolone antibiotics that were available on the market exhibited QT prolongation issues but had still received FDA approval.

ABT-773 is currently under development as "cethromycin" by Advanced Life Sciences ("ALS"), under a license from Abbott, and ALS announced results from its most recent clinical trial on June 21, 2007. Cethromycin "achieved positive safety results in the study" and "liver function tests and electrocardiogram monitoring demonstrated no significant differences between subjects receiving cethromycin and subjects receiving Biaxin," an antibiotic that is currently on the market today. ALS has recently confirmed that it is continuing to develop the compound for once-a-day dosing and expects to file for regulatory approval.

(b) Proposed Substitute Findings: In discussions with Abbott, the FDA indicated that, prior to approval, it wanted to determine whether ketolides as a class had any of the QT or liver issues that had been experienced by some macrolides. The FDA therefore requested that Abbott conduct a single two-week additional dog toxicity trial to evaluate the QT potential of ABT-773. This was not unusual, nor did it raise any concerns regarding the development of ABT-773. In Abbott's experience, it was normal at that early phase that the FDA request additional animal studies. During the November 20, 2000, FDA meeting, Abbott noted that there was nothing significant in the safety data from the Phase I and II trials. QT and liver toxicity issues, along with all of the other issues that face drug development compounds, could not be resolved until the conclusion of the clinical trials, including the Phase III clinical trials that were being conducted

throughout 2001. In February 2001, after the meeting with the FDA at the end of 2000, Abbott had concluded that FDA approval for ABT-773 was not a "major area of concern" because its data showed "equivalence to competitors."

- (c) <u>Proposed Substitute Findings</u>: As of March 2001, Abbott believed there was a high probability of achieving once-a-day dosing for the two less severe (and more commercially significant) indications, pharyngitis and chronic bronchitis, with a possibility of once-a-day dosing for the two more severe indications, CAP (community acquired pneumonia) and sinusitis (chronic sinus infection). Abbott was awaiting data from an ongoing Phase III trial that was expected to be released in the second quarter of 2001 before deciding whether 150 mg, once-a-day dosing would be viable for the more severe indications.
- (d) Proposed Substitute Findings: In July 2001, the clinical data from the Phase III trial was not yet available, and Abbott was faced with a decision of whether to wait for the release and analysis of the data, and lose time on the path to regulatory approval, or make a dose decision for the more severe indications based on the available data. In order to minimize risk and avoid delays on the path to regulatory approval, Abbott decided to plan for a launch of CAP and sinusitis with twice-a-day dosing.

 Abbott planned to continue to develop once-a-day dosing for those indications, however, and offer once-a-day dosing in the second year after launch. Abbott also continued to believe that it would be able to achieve once-a-day dosing at launch for the two less severe indications.
- (e) <u>Proposed Substitute Findings</u>: The ABT-773 ARP states that the indications for ABT-773 are "Adult Tablet" and "I.V." and that Abbott did not plan to

spend any money on pediatric or taste testing studies for the oral formulation in 2001.
Hancock did not give a copy of the Annual Research Plan, which included this disclosure, to Dr. Klotz. The ABT-773 Descriptive Memorandum states that an "oral formulation" would "enabl[e] penetration" into the pediatric market but makes no representations regarding the timing of the program. While the oral suspension formulation had some negative taste issues, Abbott planned to modify the oral suspension formulation to improve the taste.

- after a pharmaceutical company has acquired a significant amount of adult data since it is generally judged unacceptable to expose children to products without having demonstrated substantial activity in humans first and safety in adults first. The ABT-773 pediatric program was only temporarily on hold and only "unfunded" for calendar year 2001. Abbott was projecting spending \$9 million on the ABT-773 pediatric program in 2002 and \$21.5 million in 2003. By September 2001, the ABT-773 team believed that formulation work on the pediatric program could begin in mid-October and that Abbott would be able to do the first clinical study six months after that date. Abbott was not planning on filing with the FDA until August 2002, so starting a pediatric trial in 2002 would allow it to meet that obligation.
- 116. <u>Proposed Substitute Findings</u>: The regulatory hurdle with regard to ABT-773 changed dramatically in April 2001. In April 2001, the FDA held its first advisory meeting for Ketek, a ketolide that was under development by another pharmaceutical company, Aventis, and was at a more advanced stage of development than any other ketolide. Abbott had expected that the Ketek advisory would probably be related to

concerns about efficacy and not related to QT concerns. In fact, the Ketek advisory focused heavily on the size of Ketek's safety database for both QT prolongation and liver toxicity. The Ketek advisory also increased the hurdle for Abbott to develop a resistance claim for ABT-773. The Ketek advisory raised the bar for the development of ABT-773 significantly by making it clear to Abbott that the FDA would in the future require very greatly increased numbers of patients in clinical trials, in order for a drug company to establish that there were no QT prolongation and liver toxicity issues with its compound. As a result of the Ketek advisory, Abbott also learned that the FDA was increasing the stringency of the regulatory standards that were going to be required for all antibiotics. Id. The new regulatory hurdles announced by the Ketek advisory led Abbott to believe that the ABT-773 program would be longer and much more expensive than previously expected.

Other unexpected negative information also became available after April 2001. For example, in the Fall 2001, ABT-773 failed a key clinical trial for pharyngitis resulting in loss of that commercially important indication. In addition, the M01-325 clinical trial, which began on October 3, 2001, was put on hold due to unexpected liver elevations seen in four patients. These liver results were unknown to Abbott as of the date of the RFA, and were more significant in light of the new information available to Abbott about the regulatory requirements set forth by the FDA at the April 2001 Ketek advisory meeting. For example, Abbott now knew that Ketek had been required to conduct an additional 20,000 patient study because of two incidents of severe liver test results.

Abbott's Pharmaceutical Executive Committee ("PEC") met in December 2001 to discuss the new information that had become available since April 2001 with regard to ABT-773. Based on that new information, the PEC decided to continue the development of ABT-773 but not to initiate new studies or projects for the compound. The ongoing studies were continued through the winter of 2001 and the spring of 2002.

- 117. Proposed Substitute Findings: Abbott's internal documents reflect the impact of the negative information that became available to Abbott after execution of the RFA. In September 2001, a presentation to Abbott's Board of Directors noted that the Ketek advisory had caused a delay in ABT-773 development. A January 2002 memorandum prepared for Miles D. White, Abbott's Chief Executive Officer, identified the recent developments, noting, for example, that the mid-April 2001 Ketek advisory required large safety and resistance databases for Ketolide anti-infectives and that the loss of pharyngitis indication impacted the program financially and impacted the regulatory approval process. The memorandum concluded that the drug was still technically approvable with cost and time penalties, but the commercial attractiveness had decreased substantially. In January 2002, Mr. White attended a presentation regarding ABT-773 at which it was explained that the expected net present value of ABT-773 had decreased substantially since July 2001.
- 118. Proposed Substitute Findings: In February 2002, Abbott conveyed to its employees that there would be a delay in the development timeline of ABT-773. In February 2002, Abbott developed a "Global Communication Plan" regarding the potential discontinuation of development of ABT-773 but no final decision regarding whether to discontinue to program had been made at that time, and clinical trials were

ongoing. In an April 15, 2002 email to Dr. Leonard, Mr. Leiden provided an accurate report regarding Abbott's internal evaluations with regard to ABT-773 to be conveyed to Hancock. Through June 2002, there were ongoing Phase III clinical studies for ABT-773 and Abbott was evaluating the results of those trials. In the summer of 2002, Abbott decided to suspend further internal development of ABT-773 in the United States and Europe, while continuing its collaborative efforts with a Japanese pharmaceutical company to develop the compound for the Asian market.

- 119. Proposed Substitute Findings: *Supra*, ¶ 118.
- 120. Proposed Substitute Findings: *Supra*, ¶ 118.
- 121. <u>Proposed Additional Findings</u>: *Supra*, ¶ 118.
- 122. Proposed Substitute Findings: *Supra*, ¶ 118.
- 123. No proposed additional or substitute facts.
- 124. Proposed Substitute Findings: In December 2001, after the December 2001 meeting, Thomas Lyons, Controller of Abbott's Global Pharmaceutical and Development Division, informed Mr. Blewitt that ABT-773 was under review and might be terminated. On July 30, 2002, Mr. Lyons informed Hancock by telephone that Abbott would not independently advance the development of ABT-773 in the United States and Europe. This oral report satisfied Abbott's obligations under the RFA, because the RFA does not require that Abbott inform Hancock in writing of its decision to terminate a compound.
- 125. <u>Proposed Substitute Findings</u>: Abbott disclosed the true prospects and conditions of ABT-773 to Hancock as of March 2001 in the RFA.

- 126. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent or fail to disclose material information concerning the prospects and condition of ABT-773 to Hancock in the RFA.
- 127. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA because it did not misrepresent or fail to disclose material information concerning the prospects and condition of ABT-773 to Hancock in the RFA.
- 128. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent or fail to disclose any material information concerning the prospects and condition of ABT-773 to Hancock in the RFA. Abbott did not engage in any fraudulent or wrongful conduct or act with any fraudulent or wrongful intent.
- 129. Proposed Substitute Findings: Abbott informed Hancock of the true material prospects and condition of ABT-773 as of March 13, 2001. The allegedly misrepresented and omitted information was not material and would not have significantly altered the economics and attractiveness of the proposed deal from Hancock's perspective nor would it have caused Hancock not to enter into the deal in its present form or to decline to enter into any agreement whatsoever.

For example, ABT-492, a quinolone antibiotic, was a compound in the Hancock basket of program compounds. Unlike ketolides, such as ABT-773, there was evidence of a potential QT and liver toxicity issue with respect to the quinolone class.

Accordingly, in the Descriptive Memorandum for ABT-492, Abbott specifically discussed the potential for both QT prolongation and liver toxicity for the entire quinolone class of antimicrobials. Despite these disclosures by Abbott regarding the potential for QT prolongation and liver toxicity for the entire quinolone class of

antibiotics, recent quinolone withdrawals from the market, and increased regulatory scrutiny regarding quinolones, Hancock entered into the RFA with ABT-492 as part of the basket of compounds.

130. <u>Proposed Substitute Findings</u>: Hancock has not suffered monetary or other damages as a result of Abbott's alleged misrepresentations or omissions with regard to ABT-773.

Abbott Provided Hancock with Its Intended and Reasonably Expected Spending on the Program Compounds in All of Its Annual Research Plans

131. <u>Proposed Substitute Findings</u>: The RFA provides that the "Annual Research plan shall be prepared by Abbott and presented to John Hancock at least forty-five (45) days prior to the start of each Program Year." The Annual Research Plan is defined in Section 1.6 of the RFA as

a reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for every Program Year remaining in the Program Term, it being understood that less detail shall be required for Program Years that are not the current Program Year. . . .

Abbott also represented that the first ARP attached to the RFA provided a

description of . . . projected costs to be incurred by Abbott during the Program Term, for each Program Compound. Such projections were prepared in good faith and with due care based on reasonable assumptions, and represent the reasonable estimate of Abbott based on information available as of the date of such projections and as of the date hereof; it being agreed that such projections do not constitute any warranty as to the future performance of the Program Compounds and that actual results may vary from such projections.

132. Proposed Substitute Findings: Section 3.4(iv) of the RFA provides:

If Abbott: . . . (iv) does not reasonably demonstrate in its Annual Research Plan its intent and reasonable expectation to expend on Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target, John Hancock's obligation to make any remaining Program Payments for any succeeding Program Years pursuant to Section 3.1 shall terminate. For the avoidance of doubt, the Program Payments for the Program Year in which such event occurs shall still be due and payable, adjusted only as set forth in the next sentence, if applicable.

- expenditures on Program Related Costs in ARPs that it provided to Hancock. The Research Program cost projections that Abbott provided to Hancock reflected a "reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program." Abbott was not required under the RFA to report its risk-adjusted expected spending to Hancock. Although Abbott's Decision Support Group uses the term "expected" spending to refer to risk-adjusted spending calculations, these projections are for decision analysis and portfolio analysis purposes and do not represent what Abbott has budgeted or actually intends or expects to spend on a given compound.
- 134. <u>Proposed Substitute Findings</u>: At all relevant times, the various ARPs, including the ARP for 2002, provided Hancock with a "reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program."
- 135. <u>Proposed Substitute Findings</u>: Abbott's intent and reasonable expectation at the end of 2001 was to spend in excess of \$614 million on Program Related Costs during the four-year Program Term.

- 136. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent its intended and reasonable expected spending in the various ARPs, including its ARP for 2002 and Hancock did not actually and justifiably rely on the alleged misrepresentations in the ARPs regarding Abbott's spending.
- 137. <u>Proposed Substitute Findings</u>: Abbott's ARPs did not misrepresent Abbott's intended and reasonably expected spending and Abbott did not breach the RFA.
- 138. <u>Proposed Substitute Findings</u>: Abbott's ARPs did not misrepresent Abbott's intended and reasonably expected spending and Abbott did not act fraudulently or wrongfully.
- 139. <u>Proposed Substitute Findings</u>: Abbott did not misrepresent its intended and reasonably expected spending in the various ARPs, including its ARP for 2002. Hancock was not excused from making its Second Program Payment in the amount of \$54,000,000 in January 2003.
- 140. Proposed Substitute Findings: Abbott reasonably demonstrated in its first and second ARPs its "intent and reasonable expectation to expend on Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target . . ." pursuant to Section 3.4 of the RFA. Even if Abbott had reported its risk-adjusted spending, as Hancock contends was required under the RFA, Abbott's projected expenditures on Program Related Costs during the Program Term, as of the date of its second ARP, still would have been in excess of \$614 million, therefore, Hancock still would have been required to make its Second Program Payment of \$54 million. Thus, Hancock has not suffered monetary or other damages due to any alleged misrepresentations, omissions or fraud in Abbott's various ARPs.

Page 54 of 103

141. Proposed Substitute Findings: Reading the Agreement as a whole, and giving effect to all its provisions and the intent of the parties, the Aggregate Spending Target of \$614 million is comprised of Abbott's required minimum contribution of \$400 million and Hancock's maximum contribution of \$214 million. Section 3.1 defines "Program Payments" as a series of installment payments totaling \$214 million that Hancock "shall make . . . to Abbott to help support the Research Program." Section 3.5 provides that Abbott shall be responsible "for funding all Program Related Costs in excess of the Program Payments from John Hancock." In other words, "Hancock would commit to providing approximately 50 million per year to Abbott over a four year period" and "Abbott would spend at least \$100 million of its own funds on the development of the compounds during this same period[.]"

Section 3.4, titled "Termination of John Hancock's Program Payment Obligation," sets forth the circumstances in which Hancock is relieved of its obligation to make future installments of its Program Payments, and sets forth the rights and obligations of the parties in such circumstances.

- 142. No proposed substitute or additional findings.
- 143. No proposed substitute or additional findings.
- 144. No proposed substitute or additional findings.
- 145. Proposed Substitute Findings: In *Hancock I*, Hancock obtained a declaratory judgment that, under Section 3.4, Hancock was relieved of its obligation to make its third and fourth Program Payments, totaling \$110 million. Accordingly,

Page 55 of 103

Hancock only made \$104 million in Program Payments, rather than the maximum of \$214 million.

- Proposed Substitute Findings: Abbott's actual spending on Program 146. Related Costs over the four-year Program Term was approximately \$456.3 million (including all milestone and management fees paid by Abbott to Hancock, which qualify as Program Related Costs under Section 1.43 of the RFA).
- 147. Proposed Substitute Findings: In Hancock I, Hancock obtained relief from \$110 million in Program Payments pursuant to Section 3.4 after Abbott provided advance notice to Hancock that it would not spend in excess of \$614 million in Program Related Costs during the Program Term. Abbott was not required to make up the shortfall caused by Hancock's termination of Program Payments, nor is Hancock entitled to additional relief under Section 3.3(b).

The parties' intent and understanding of Section 3.3(b) did not require Abbott to make up for a shortfall caused by Hancock's termination of payments pursuant to Section 3.4 of the RFA. Section 3.3(b) was intended to provide Hancock with a refund in situations where it had made its final Program Payments based on Abbott's stated intention to spend more than the Aggregate Spending Target, but Abbott had unexpectedly fallen short of the target in the Program Term and the subsequent year.

By contrast, Section 3.4 was intended to address situations in which Abbott provides advance notice of its intent to "reduce its planned spending" below the Aggregate Spending Target. In such circumstances, Section 3.4 provided that Hancock's remedy would be termination of its Program Payments. During negotiations of the RFA, Hancock never indicated that it believed Abbott would be required by Section 3.3(b) to

increase its spending to make up for a shortfall caused by Hancock's termination of payments pursuant to Section 3.4.

Other evidence also shows that the parties intended for Abbott to be required to spend \$400 million of its own funds, plus Hancock's Program Payments, and did not intend for Abbott to be required under Section 3.3(b) to make up for a shortfall caused by Hancock's termination of payments pursuant to Section 3.4:

- During negotiation of the Agreement, Hancock's attorneys (Choate, Hall, and Stewart), sent a memorandum to Abbott representatives noting that "our understanding" of the Agreement (which at that time provided for an Aggregate Spending Target of \$620 million) is that "Abbott would be obligated to fully fund its share of the Aggregate Spending Target (that is, \$400,000,000 of the \$620,000,000 total amount)."
- An internal Abbott summary of the Agreement explained that Section
 3.3(b) applies if Abbott "does not spend the Aggregate amount of \$400 million by the end of the 4th year (in addition to the John Hancock payments)."
- Mr. Blewitt's sworn testimony by affidavit filed in *Hancock I* stated that:

Abbott, for its part, agreed to spend at least \$400 million of its own funds on Program Related Costs over the four-year Program Term, and to make certain milestone and royalty payments to John Hancock depending on the progress and commercial success of the Program Compounds The combined total of John Hancock's maximum funding contribution and Abbott's minimum funding contribution (i.e. \$614,000,000) is defined in the Agreement as the "Aggregate Spending Target."

Hancock has contended that references to "Abbott's minimum funding contribution" indicated that the parties understood that Abbott might be

required to spend more than \$400 million of its own funds. However, the reference to "minimum" is more reasonably understood as a reference to the floor on Abbott's contribution, with an understanding that Abbott would spend more than that amount if the compounds continued to be successfully developed.

- Brewster Lee of Choate Hall & Stewart, Hancock's lead attorney in negotiation and drafting of the Agreement, testified that he understood—based on the wording of the Agreement and his own general understanding of the deal—that Abbott was required to spend a minimum of \$400 million of its own funds on development of the Program Compounds, in addition to the funds provided by John Hancock. He and his colleague, Kevin Tormey, sent a memorandum to Abbott on September 18, 2000 stating that it is "our understanding" that Abbott's share of the Aggregate Spending Target would be \$400,000,000 of the \$620,000,000 total amount," and he had no reason to doubt the accuracy of that statement. He testified that the Aggregate Spending Target was comprised of Abbott's share of the Aggregate Spending Target (i.e., \$400 million), plus the Hancock Program Payments.
- Scott Hartz, Hancock's Head Portfolio Manager who analyzed the
 proposed deal with Abbott, and helped draft a report recommending its
 approval by Hancock management, testified that it was his understanding
 that Abbott was required to spend a set amount of funds on development

- of the Program Compounds, over and above the amount of funds provided by Hancock.
- The parties routinely adjusted the Aggregate Spending Target during drafting of the Agreement so that it was the total of the Hancock Program Payments (the exact amount of which varied during negotiations) plus Abbott's share of the Aggregate Spending Target (i.e., \$400 million). The first draft of the agreement prepared by Abbott defined Program Payments as a series of installment payments totaling \$220 million and set the Aggregate Spending Target at \$620 million. Later, the Program Payments were changed from \$200 to \$218, and the Aggregate Spending Target was changed from \$600 to \$618 million. Finally, the parties changed the Program Payments to \$214 million and the Aggregate Spending Target to \$614 million. Mr. Blewitt conceded at his deposition that the Aggregate Spending Target was regularly adjusted so that it equaled \$400,000 plus the maximum that Hancock was obligated to spend under Section 3.1.
- During the negotiation of the RFA, the parties decided not to include a term, originally proposed by Hancock, providing that nothing in Section 3.4 would "relieve Abbott of any of its responsibilities under this Agreement."
- On September 21, 2000, Mr. Blewitt and Mr. Hartz submitted a report to the Bond Investment Committee recommending approval of the terms of a substantially similar prior draft of the Agreement. In the report, Mr. Blewitt and Mr. Hartz explained that they were "recommending a \$220

million commitment" by Hancock subject to Abbott "co-funding at least two times our commitment." They noted that Hancock "shall make" Program Payments of \$220 million over four years and that "[d]uring the Program Term, Abbott agrees to spend, in addition to the funds provided by John Hancock . . . (ii) a minimum of \$400 million in aggregate on research and development programs associated with the Program Compounds."

- Similarly, an Abbott presentation prepared by Steve Cohen, then

 Controller and head of finance for Abbott, with assistance from Mr.

 Deemer, indicated that the "John Hancock \$ Contribution" was \$200

 MM" and that the "Abbott \$ Contribution Requirement" was a

 "cumulative" total of "\$400 MM." Roger Nastou, the head of Hancock's

 Bond and Corporate Finance Department who attended Mr. Blewitt's

 presentation to the Bond Investment Committee and presented the

 proposed deal to Hancock's Committee of Finance for final approval,

 testified that he understood that Abbott was required to spend a specified

 amount of money in addition to the funds invested by John Hancock. Mr.

 Nastou did not recall any agreement that Abbott would spend a specific aggregate amount of funds on development of the Program Compounds, irrespective of the amount of funding provided by Hancock.
- 148. <u>Proposed Substitute Findings</u>: *Supra*, ¶ 147.
- 149. <u>Proposed Substitute Findings</u>: *Supra*, ¶ 147. Abbott's actual spending on Program Related Costs in 2005 was approximately \$73.0 million.

- 150. <u>Proposed Substitute Findings</u>: *Supra*, ¶¶ 141-49.
- 151. <u>Proposed Substitute Findings</u>: *Supra*, ¶¶ 141-49.
- 152. <u>Proposed Substitute Findings</u>: *Supra*, ¶¶ 141-49.
- 153. Proposed Substitute Findings: Abbott did not breach Section 3.3(b) of the RFA. In addition to being inconsistent with the language of the RFA when read as a whole, Hancock's interpretation of Section 3.3(b) would produce a commercially irrational result that the parties could not have intended. If Section 3.3(b) were interpreted in these circumstances as Hancock urges, it would also constitute a penalty clause that is unenforceable under Illinois law. *See* Abbott's Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law, paragraphs 65-68 and 128 to 132.²
- 154. <u>Proposed Substitute Findings</u>: Since Section 3.3(b) of the RFA is inapplicable, Hancock did not suffer monetary or other damages. If Section 3.3(b) were applicable and Abbott were liable, the actual damages would be \$28.2 million.

Abbott Complied With Its Audit Obligations Under the RFA

155. <u>Proposed Substitute Findings</u>: Section 2.5 of the Agreement provides, in part, that:

Abbott shall, and shall cause each Subcontractor to, maintain complete and accurate records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and for purposes of demonstrating compliance with the terms hereof, that fully and properly reflect all work done, results

has included the arguments in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of

4881848.1

Law.

² Pursuant to the Court's Second Amended Order Regulating Non-Jury Trial, each party is required to file Proposed Findings of Fact and Conclusions of Law on any claim or defense for which it has the burden of proof. Abbott's Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law sets forth Abbott's argument that Hancock's interpretation of Section 3.3(b) would constitute an unenforceable penalty. Abbott does not concede, by including this argument, and other arguments, in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law, that it bears the burden of proof on these issues. However, in an abundance of caution, Abbott

achieved and Program Related Costs expended in performance of the Research Program. The books and records of Abbott and each Subcontractor related to the Research Program, including, without limitation, those related to the expenditure of Program Related Costs, shall be subject to copying, inspection and audit by (and at the expense of) John Hancock at any time and from time to time. Such audit shall occur on reasonable notice and during normal business hours by an independent auditor selected by John Hancock and reasonably acceptable to Abbott. John Hancock and its independent auditor shall maintain such records and information of Abbott in confidence in accordance with Article 10 and shall not use such records or information except to the extent permitted by this Agreement, including any enforcement of the provisions hereof. In the event that such audit reveals any material breach of Abbott's responsibilities hereunder, Abbott shall (i) pay the reasonable fees and expenses charged by such auditor, and (ii) fully and promptly cure such breach.

- 156. Proposed Substitute Findings: At a March 30, 2004 hearing in *Hancock I*, Hancock sought generalized discovery concerning the Program Compounds, stating that it hoped such discovery would provide the basis for additional claims against Abbott. The Court denied Hancock's request, holding that the *Hancock I* complaint was "not a vehicle for providing generalized discovery into the parties relationship." Two weeks later, Hancock made a demand for an audit under Section 2.5 of the Agreement in a letter dated April 12, 2004. The audit demand identified individuals from the StoneTurn Group, LLP, including Christopher Martinez and Brian Napper, as the "independent auditors retained by John Hancock" pursuant to Section 2.5 of the Agreement.
- 157. <u>Proposed Substitute Findings</u>: Although Section 2.5 of the Agreement does not specify any particular documents that must be created or maintained by Abbott, Hancock's April 12, 2004 audit demand included as "Schedule A," a "preliminary list" of 30 or more particular categories of documents sought by the audit. Hancock's audit demands were unduly burdensome and overbroad. For example, among other things, the

Page 62 of 103

"preliminary list" provided by Hancock sought "[u]nderlying supporting records (e.g., timesheets, payroll records, purchase orders, invoices, etc.) for all expenditures made related to each Program Compound." During the period 2001–2004, Abbott had made expenditures of nearly a half a billion dollars on the Research Program. Thus, even this one category of the audit demand alone sought a massive quantity of documents.

- 158. Proposed Substitute Findings: Hancock's audit demand unilaterally set the date of May 12, 2004, which was 30 days from the date of the demand, for commencement of the audit.
- 159. Proposed Substitute Findings: Hancock's audit demands were unreasonable, unduly burdensome, and made for litigation purposes, rather than for purposes of a contractual compliance audit. Abbott's response to the audit was reasonable and in compliance with Section 2.5 of the Agreement.
- Proposed Substitute Findings: In response to Hancock's audit demand, 160. Abbott acted reasonably and in compliance with its obligations under Section 2.5 of the Agreement.
- (a) Proposed Substitute Findings: Abbott's outside counsel Winston & Strawn LLP ("Abbott's counsel") consulted with outside counsel for Hancock, Choate, Hall & Stewart LLP ("Hancock's counsel") regarding Hancock's selection of The StoneTurn Group ("StoneTurn") as Hancock's "independent auditor." Section 2.5 of the Agreement required that Hancock's selection of an auditor be "reasonably acceptable" to Abbott. After it was disclosed that other representatives from StoneTurn, while at a different firm, had rendered services to Hancock's counsel on other matters, there was a joint telephone conference among the representatives of StoneTurn, Hancock's counsel, and Abbott's

counsel. The joint telephone conference revealed to Abbott, among other things, that StoneTurn was principally in the business of providing litigation support and expert witness services to law firms, rather than conducting independent audits. In the course of this telephone conference, Abbott objected to StoneTurn and Messrs. Martinez and Napper as independent auditors, but to avoid further debate with Hancock, offered to permit them to proceed with their audit with certain understandings. Without waiving its objections to StoneTurn, but rather to avoid further debate and to allow the audit to proceed, Abbott's counsel informed Hancock's counsel, in a letter dated June 23, 2004, that Abbott was willing to allow StoneTurn to proceed, beginning on June 30, 2004. Hancock was notified that Abbott would begin making documents available for inspection on June 30, 2004, during normal business hours, at a facility located in Mundelein, Illinois, and that Abbott paralegal Michelle Campbell would act as StoneTurn's contact at Abbott for purposes of the audit.

(b) Proposed Substitute Findings: After Abbott received Hancock's April 12, 2004 audit demand, Abbott's counsel communicated with Hancock's counsel for the purposes of attempting to negotiate the scope and timing of Hancock's audit demand. In a letter dated May 3, 2004, Abbott's counsel notified Hancock's counsel of Abbott's belief that the audit demand was overly broad and unduly burdensome, and requested a meeting with Hancock to explore whether less burdensome alternatives existed to certain requests made by Hancock that would still provide Hancock the information it needed, as well as to discuss a more realistic timeframe to gather and produce the materials Hancock requested. In response, Hancock's counsel wrote that Hancock would be willing to consider whether less burdensome alternatives to its audit demand existed *only after*

Hancock's auditors obtained access to the information sought by Hancock's audit demand, beginning on the original date chosen by Hancock, and then provided that information to Hancock.

Shortly after receipt of the audit demand, Abbott began the process of identifying and collecting documents to be produced in response to Hancock's audit demand.

Documents responsive to Hancock's audit demand were made available to StoneTurn beginning on June 30, 2004. Because of the large volume of materials involved, and the commercial sensitivity and need for confidentiality of many of the materials, the production of audit materials occurred on a rolling basis through the first week of March 2005. Abbott had originally expected to be completed with its audit production by January 31, 2005, but was not able to do so because of the extensive scope of Hancock's audit demand and the complicated nature of the redaction necessary to ensure the protection of Abbott's highly confidential information unrelated to the Research Program.

The first group of the documents produced in response to Hancock's audit demand was inspected by individuals from StoneTurn on June 30, July 1, 7, 8, and 9, 2004. By the end of July 2004, Abbott had made approximately 750 boxes of documents available to StoneTurn. Production of the remaining documents in response to Hancock's audit demand was made throughout the remainder of 2004 and early 2005. Portions of the remaining materials contained information unrelated to the Research Program, which required additional sorting and redaction that slowed down the production of materials as compared to the initial wave of production of predominantly unredacted materials. This consisted of approximately an additional 50 boxes of

documents made available for inspection and from which Hancock's auditors identified documents for copying and delivery.

(c) Proposed Substitute Findings: In total, in response to Hancock's audit demand, Abbott collected and made over 800 boxes of documents available to Hancock for inspection. After a reasonable investigation, Abbott determined that the relevant books and records of Abbott to be produced in the audit were kept and maintained in at least four different ways: (1) at the "RIC" Research Information Center; (2) at Corporate Records; (3) in shared drives among relevant departments; (4) and in databases and portals set up by individual areas.

Each of these specific areas in which relevant records were housed, and the scope of Abbott's collection of records from those areas, is described below:

- RIC. The RIC, or Research Information Center, of Abbott is a records management service that Abbott uses to maintain all of its clinical/FDA records. It is separate from Corporate Records because it has its own rules that are intended to comply with FDA guidelines for retention and storage. The RIC maintains extensive materials regarding Abbott's clinical programs, including regulatory filings, trial master files, clinical reports, specimens, and laboratory notebook supplements. Abbott collected and made available to Hancock's auditors all materials in the RIC relating to the Research Program with the exception of specimens and laboratory notebooks, which were not responsive to the audit.
- Corporate Records. Unlike the RIC records, the documents stored in "Corporate Records" are not limited to a particular kind of document or document(s), such as those relating to FDA approval. Instead, any Abbott employee can

place any kind of written material into Corporate Records. Examples of some types of documents that typically are housed within Corporate Records, and which generally are not maintained within the RIC, are timesheets, underlying expense back up, invoices, purchase orders and other voluminous data. In addition, corporate records includes "governmental submission" documents, such as reports filed with the FDA regarding Abbott's research and development of compounds. Abbott collected and made available all relevant government submissions in Corporate Records, which to some extent may have overlapped with some RIC documents. Additionally, Abbott collected individual time sheets from Corporate Records, and those time sheets were initially produced to Hancock's auditors, until Abbott was instructed by Hancock's counsel and auditors to stop producing this category of information.

- Shared Drives. Shared drives are computer hard drives located on Abbott's internal computer network that are segregated within Abbott by department. Each therapeutic area (as well as the accounting and financial areas) have a separate shared drive. In the financial areas, shared drives were used to save, among other things, budget proposals, presentations to management related to financial issues, and work papers. In the therapeutic areas, final papers, study protocols, research memoranda and other draft documents were saved. The relevant shared drives were searched for these documents and produced in the audit to the extent they related to the Research Program.
- Databases and Portals. Another source of documents for the audit was a database which crosses therapeutic areas called the MPSR, which stands for the Monthly Project Status Report database. The MPSR contains project status reports, including Monthly Highlights Memoranda, Monthly Compound Project Status Reports,

PARD reports or other monthly reports. All status reports within the MPSR database for the period March 2001 to the date of the audit production were collected for each of the compounds in the Research Program and made available to Hancock's auditors for inspection.

Abbott's oncology group, which was responsible for four of the nine compounds subject to the Agreement, "maintained two other databases that are referred to internally as 'portals." Some of the data contained in these portals is duplicative of the MPSR database. Nevertheless, these portals were searched for documents pertaining to the Research Program, and relevant documents from these portals were made available to Hancock's auditors for inspection.

With respect to financial and accounting documents, there were three additional databases or systems that were searched for documents concerning the Research Program. First, Abbott searched for documents pertaining to the Research Program from the so-called "R/oss" database, which tracks external expenditures on development of compounds. Second, Abbott searched for documents pertaining to the Research Program in the COMPASS database, which stands for Comprehensive Project Accounting System. The COMPASS database tracks all expenses by project. Project reports were generated from these two databases for the Research Program and were made available to Hancock's auditors in the audit. Third, Abbott searched for relevant materials in the Optika system, which is an accounts payable system into which Administrative Check Request ("ACR") backup is scanned.

• **Desk Files.** Abbott did not as a general matter collect and produce to Hancock's auditors the emails and individual desk files of the numerous Abbott

employees who may or may not have maintained individual files pertaining to the Research Program. Rather, Abbott collected and produced its company files, as described above, which were sufficient to "fully and properly reflect all work done, results achieved and Program Related Costs expended in performance of the Research Program" under the Agreement. These company files constitute complete and accurate records, maintained in the routine course of Abbott's business, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and for purposes of demonstrating compliance with the terms of the Agreement. Hancock's counsel was informed that Abbott's audit production did not include the desk files of individual Abbott employees.

For out-licensing materials, unlike the therapeutic and financial/accounting areas discussed above, there was not a database or a shared drive containing company files; accordingly, relevant files were gathered from the individuals John Moore, Tony Deahl, Steve Mickel, Kevin Constable, and Michele Parks. In addition, some files were collected from Stan Bukofzer and Tom Woidat. These individuals' files were reviewed for privilege and then the relevant, non-privileged documents were made available to Hancock's auditors for inspection.

In 2004–05, while the audit was in progress, Abbott also produced documents, including emails and desk files, to Hancock in *Hancock I*. Hancock has admitted in an interrogatory response that it gained knowledge of the alleged misrepresentations regarding ABT-518 in June 2004 from documents produced in *Hancock I* and knowledge of the alleged misrepresentations regarding ABT-594 and ABT-773 in "Fall/Winter 2004" from documents produced by Abbott in the audit. Abbott also made witnesses

available for deposition in the *Hancock I* action. In addition, in June 2005, shortly after completion of the audit, Hancock filed the present action, in which it obtained additional discovery regarding Abbott's compliance with the Agreement.

- (d) Proposed Substitute Findings: Once Abbott gathered documents, depending on the type of document or source, it made a judgment as to whether the documents reasonably could be determined to be related only to the Research Program. If that was the case, the records were made available for inspection by Hancock's auditors without further review or redaction by Abbott. Documents of this nature, which did not require further review or redaction, were produced first, which was the most efficient manner in which to proceed, particularly given Hancock's timing demands. If Abbott believed there existed a risk of disclosure of confidential information pertaining to compounds other than the Research Program, such as when information concerning the Research Program was contained in documents that also provided information about non-Research Program activities, the documents were reviewed and information unrelated to the Research Program was redacted. In the present action, pursuant to a discovery request, Abbott produced to Hancock—subject to the confidentiality provisions of the Protective Order—unredacted copies of documents it had previously provided to StoneTurn in redacted form.
- (e) <u>Proposed Substitute Findings</u>: Section 2.5 only required Abbott to make available books and records "related to the Research Program," not records relating to other aspects of Abbott's business. Abbott's withholding of documents unrelated to the Research Program, and redaction of portions of documents that were unrelated to the Research Program, was reasonable and did not constitute a breach of Section 2.5.

Case 1:05-cv-11150-DPW

Although Messrs. Martinez and Hair referred to a "GPRD Quality Assurance Monthly Highlights" document from December 2003 that was produced in redacted form, there is no evidence that the unredacted document contained any significant relevant information regarding the Program Compounds. More generally, although StoneTurn (at the direction of Hancock's counsel) compared redacted documents produced in the audit to unredacted documents produced in the litigation to determine the relevance of information that was redacted, the StoneTurn witnesses did not offer any specific examples of relevant and responsive information regarding the Program Compounds that was redacted. In addition, Abbott had no obligation under Section 2.5 to disclose information protected by the attorney-client privilege or work product, therefore, its withholding and/or redaction of such information was not a breach of Section 2.5.

- (f) Proposed Substitute Findings: Abbott's counsel explained to Hancock's counsel that Abbott was withholding various documents that were unrelated to the Research Program or privileged, and redacting of portions of documents that were unrelated to the Research Program or privileged, in order to protect commercially sensitive and/or privileged information. Abbott did not have an obligation under Section 2.5 to provide a log of such documents or redactions.
- Proposed Substitute Findings: Hancock's April 12, 2004 audit demand (g) requested that documents be "made available for its inspection and audit." Hancock did not initially request that it be allowed to make its own photocopies of the books and records, but instead stated that "[i]n accordance with Section 2.5 of the Agreement, John Hancock reserves the right to designate for copying . . . any or all of the books and records of Abbott that are subject to its inspection and audit." (emphasis added). Abbott

permitted Hancock's auditors to physically review and take notes regarding the documents produced by Abbott and to designate particular documents for photocopying and later delivery. Only after the audit was underway did Hancock request the ability to bring its own photocopying equipment into Abbott's facilities for the purpose of making copies of the audit documentation produced by Abbott. In order to ensure that Abbott maintained proper control over the copying and removal of its materials from its premises, Abbott's counsel informed Hancock's counsel that Abbott would continue to make arrangements to copy materials designated by StoneTurn and to deliver such copies to StoneTurn.

- (h) <u>Proposed Substitute Findings</u>: Abbott generally copied documents selected by StoneTurn promptly and did not intentionally or unreasonably delay copying of any nonprivileged books and records that were properly subject to inspection under Section 2.5 and designated for copying by Hancock.
- (i) <u>Proposed Substitute Findings</u>: Abbott copied all of the documents designated by StoneTurn and provided them to StoneTurn, except where Abbott determined that certain privileged and/or non-responsive documents, inadvertently included for inspection in a so-called "Box 17," were selected for copying by Hancock's auditors. These certain documents were ultimately withheld from copying and production to Hancock's auditors, and Hancock's counsel was informed of the bases for the removal of those documents from the production to Hancock's auditors.
- (j) Proposed Substitute Findings: Abbott did not unduly delay completion of its audit response. Abbott made reasonable efforts to comply with its stated goals regarding the date of completion of its audit production. For example, Abbott had

originally informed Hancock that it expected to be completed with its audit production by January 31, 2005, but was not able to do so because of the extensive scope of Hancock's audit demand and the complicated nature of the redaction of confidential information unrelated to the Program Compounds. Abbott completed its production by March 22, 2005.

- (k) Proposed Substitute Findings: During the course of the audit, StoneTurn demanded that Abbott take actions that were not required by Section 2.5. For example, Hancock's auditors and Hancock's outside counsel requested, in addition to Abbott's production of its books and records, that Abbott prepare a log identifying the title, location, and responsiveness to Hancock's "preliminary list" of April 12, 2004 of each of the documents within the approximately 800 boxes made available to Hancock's auditors for inspection. Because Abbott concluded that this request exceeded the scope of the audit rights set forth in Section 2.5 of the Agreement and was unduly burdensome in nature, Abbott declined to comply with the request and communicated its response to Hancock's counsel. In addition, StoneTurn representatives had prepared their own index of the materials produced by Abbott in connection with the audit.
- (1) Proposed Substitute Findings: Section 2.5 requires Abbott to make its "books and records" available for "copying, inspection, and audit." It does not require Abbott to make its personnel available for interviews. Consistent with Section 2.5, Hancock's initial April 12, 2004 audit demand only requested access to "books and records" and did not request interviews with Abbott employees or the provision of any other non-documentary information. However, StoneTurn and Hancock's counsel subsequently requested interviews of Abbott personnel to ask questions that purportedly

could not be answered from an inspection of the materials produced by Abbott during the audit. Abbott's counsel informed Hancock's counsel (e.g., in an April 21, 2005 letter) that, because the Agreement did not require Abbott to provide such interviews, and because Abbott believed Hancock was attempting to utilize the audit process as a tool for conducting litigation-motivated discovery in the aid of a threatened lawsuit, Abbott declined to provide the interviews requested by Hancock's counsel. Although Abbott did not voluntarily make witnesses available for interviews in the audit, Hancock has obtained testimony from dozens of current and former Abbott employees in depositions in *Hancock I* and the present action.

(m) Proposed Substitute Findings: Abbott did not knowingly or intentionally under-fund or under-staff its response to Hancock's audit demand so as to delay the audit. To the contrary, Abbott devoted substantial resources to compliance with Hancock's audit demand, including the time of Ms. Campbell, in-house counsel Kenneth Wittenberg, Abbott's outside counsel, and non-legal personnel who participated in identification, collection, assembly, and copying of documents for production to StoneTurn. Because of the breadth and complexity of the audit production, Abbott engaged five outside contract paralegals through Manpower, Inc. (which works with contract firms such as Special Counsel) to perform the review and redaction of audit documents prior to making them available to Hancock's auditors for inspection. The contract paralegals from Manpower, Inc. were supervised by Ms. Campbell with supervisory assistance from an outside contractor, Carey Crimmons, who was also engaged to assist in the response to Hancock's audit demand. In addition, Abbott incurred significant photocopying expenses.

- (n) Proposed Substitute Findings: While Hancock has asserted that Abbott acted in a manner contrary to the usual course of contractual compliance audits, and contrary to Abbott's own conduct in reasonably similar circumstances in the past, Mr. Martinez's testimony on this point was not supported by any documentary evidence (e.g., documents reflecting the policies, practices, or procedures of StoneTurn and/or Mr. Martinez in prior audits). In addition, StoneTurn's audit of Abbott was not a "usual" audit and the circumstances were not reasonably similar to a typical audit. The audit was conducted during pending litigation by Hancock against Abbott arising out of the RFA (Hancock I) for the express purpose of gathering documents relevant to potential new claims. The auditor selected by Hancock was StoneTurn, which primarily provides litigation consulting services, not auditing services. During the course of the audit, StoneTurn coordinated its efforts with Hancock's counsel in the *Hancock I* litigation and provided documents produced in the audit to Hancock's counsel. After Abbott became aware that StoneTurn was providing copies of documents produced by Abbott directly to Hancock's counsel, Abbott's counsel requested an identification of all such documents, but Hancock refused to provide the information. In addition, the audit was not Hancock's only means of obtaining information regarding the Research Program. Hancock was simultaneously obtaining discovery in *Hancock I* while conducting the audit. Shortly after completion of the audit, Hancock obtained additional discovery in the present action.
- 161. <u>Proposed Substitute Findings</u>: On March 22, 2005, Abbott notified Hancock that Abbott had fulfilled its obligation with respect to the audit.

- 162. <u>Proposed Substitute Findings</u>: Hancock's audit demands exceeded the legitimate rights of Hancock under Section 2.5 of the Agreement. In response to Hancock's demands, Abbott provided the books and records it was obligated to make available under Section 2.5, which records were sufficient for Hancock and StoneTurn to determine Abbott's compliance with the terms of the Agreement.
- 163. Proposed Substitute Findings: Abbott provided all of the documentation that was required under the Agreement and necessary for StoneTurn to complete its audit. Abbott's response to Hancock's audit demand allowed Hancock and StoneTurn to audit Abbott's compliance with the terms of the Agreement. Abbott produced documents relating to all of the Program Compounds. All of the documents produced by Abbott were responsive to the audit demand.

Abbott produced numerous documents relating to the pre-clinical and clinical trials of all the Program Compounds, including ABT-518, ABT-594, and ABT-773.

Abbott's production in the audit included documents reflecting the facts at issue in this case. For example, Abbott produced documents regarding the M99-114 trial, including documents reflecting interim drop-out rates, closure of enrollment in M99-114 trial at 269 patents, the final results of the M99-114 trial, case report forms, medical review notes, and screen failure reports. Abbott produced documents reflecting its 2001 budgeted and "Blue Plan" expenditures for ABT-594. With respect to ABT-594, Abbott also produced documents regarding potential follow-on compounds, internal development timelines, and efforts to improve tolerability. Abbott produced documents regarding the status of ABT-773 with respect to liver and QT safety, dosing, and the pediatric program. Abbott produced documents reflecting the status of ABT-518 and

competitor MMPI compounds as of March 2001. Abbott produced commercial forecasts reflecting "a base case, an upside and low scenarios", probabilities of success, commercial value, and expected commercial value for Program Compounds. Abbott produced documents reflecting its budgeted and projected expenditures on Program Compounds. Abbott produced documents reflecting its risk-adjusted "expected" spending. Abbott produced documents reflecting its actual expenditures on the Program Compounds, including project expense reports that delineate expenditures by month and function.

Although Hancock alleges that StoneTurn was unable to prepare an audit report,

StoneTurn and Hancock did analyze and use the information produced by Abbott in the

audit; StoneTurn provided Hancock litigation counsel with copies of documents produced

by Abbott in the audit and prepared summaries and analyses of the documents.

- 164. <u>Proposed Substitute Findings</u>: Abbott complied with its obligations to Hancock under the Agreement, including its obligations under Section 2.5.
- 165. Proposed Substitute Findings: Abbott did not hinder, delay, or obstruct Hancock's audit, and did not act with the intent to conceal alleged misrepresentations, omissions, or fraud. The StoneTurn auditors, Christopher Martinez and Mark Hair, testified that Ms. Campbell and a contract attorney retained to assist with audit response did not respond directly to various inquiries, but instead promised to forward the questions to someone in Abbott with more authority. However, Abbott's outside counsel, Winston & Strawn, was in regular communication with Hancock's outside counsel, Choate, Hall & Stewart, and provided responses to the questions raised by Hancock and its auditors regarding the audit.

166. <u>Proposed Substitute Findings</u>: Hancock did not suffer any monetary or other damages from Abbott's alleged efforts to "hinder, delay and obstruct" the audit.

Abbott Compiled With Its Contractual Obligations Under Section 4.3 Regarding Out-Licensing of ABT-518 and ABT-594

167. Proposed Additional Findings: Section 4.1 of the RFA provides that:

The obligations of Abbott, its Affiliates and Licensees with respect to any Product under this Article 4 are expressly conditioned upon the safety, efficacy, and commercial feasibility of each Product, consistent with using Commercially Reasonable Efforts.

"Commercially Reasonable Efforts" are defined in the RFA as

efforts which are consistent with those normally used by other pharmaceutical companies with respect to other pharmaceutical compounds or products which are of comparable potential commercial value and market potential at a similar stage of development or product life, taking into account, without limitation, issues of safety and efficacy, compound or product profile, proprietary status, the regulatory environment and the status of the compound or product and other relevant scientific factors.

Section 4.4 of the RFA provides that

Abbott shall not research, develop, manufacture, market, sell, distribute, out-license or otherwise treat any Program Compounds or Product differently, as compared to any other Abbott compounds or products, on account of any of John Hancock's rights hereunder." (emphasis added).

Thus, the "obligations of Abbott" with respect to outlicensing Ceased Compounds are not absolute. Abbott's obligations "are expressly conditioned upon the safety, efficacy and commercial feasibility of each Product, consistent with using Commercially Reasonable Efforts." Furthermore, the Agreement provides that any license or divestiture

is intended to benefit "both parties," not merely Hancock. Finally, the RFA provides that with respect to the sale or out-licensing of Program Compounds, Abbott is not to treat the Program Compounds differently than its other compounds, on account of Hancock's rights under the Agreement.

- 168. No proposed additional or substitute findings.
- 169. <u>Proposed Substitute Findings</u>: Abbott made commercially reasonable efforts to out-license ABT-518. Despite those efforts, Abbott was unable to out-license or divest ABT-518 to a third party.
- 170. <u>Proposed Substitute Findings</u>: Abbott complied with its contractual obligations with regard to the out-licensing of ABT-518 and did not breach the RFA.
 - 171. No proposed additional or substitute findings.
- 172. <u>Proposed Substitute Findings</u>: Abbott has not out-licensed or divested ABT-594 to a third party.
 - 173. No proposed additional or substitute findings.
 - 174. No proposed additional or substitute findings.
 - 175. No proposed additional or substitute findings.
- 176. Proposed Substitute Findings: After Abbott discontinued its development of ABT-594, only one potential licensee, Bayer Animal Health, ever expressed interest in licensing the compound, and that was for its potential development as a drug for animals. It would not have been commercially reasonable for Abbott to out-license or divest ABT-594 to Bayer Animal Health or another pharmaceutical company, particularly for development as a drug for animal health, while Abbott was developing other pain compounds (such as ABT-894) with the same mechanism of action for use in humans.

Licensing in those circumstances also would have required Abbott to treat the outlicensing of ABT-594 differently, as compared to other Abbott compounds, on account of the agreement with Hancock, contrary to Section 4.4 of the RFA.

177. Proposed Substitute Findings: Abbott complied with its obligations under the RFA with respect to out-licensing of ABT-518 and ABT-594, and Hancock has not suffered monetary or other damages as a result of the breaches alleged by Hancock. Hancock did not introduce any evidence of the fact or the amount of damages from Abbott's alleged breach of its outlicensing allegations. Although numerous companies were developing compounds in the same class as ABT-594 (i.e., NNRs) at the time of the RFA, there is no evidence that any NNR compound has been approved by the FDA and marketed to the public. There is no evidence that Bayer Animal Health or any other company would have been interested in outlicensing or purchasing ABT-594 after receiving confidential information regarding the compound (including the negative results of the Phase IIb trial), what the terms of any such agreement would have been, or what royalty or milestone payments Hancock would have received under any such agreement.

Hancock Has Not Demonstrated that It Is Entitled To Damages

178. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA or engage in fraud. Even if Hancock could prove breach of the Agreement and/or misrepresentations, the alleged misrepresentations are not of such a nature and such importance that the Agreement would not have been approved without them.

Even if the allegedly omitted material information regarding ABT-518, ABT-594, and ABT-773 would have caused Hancock to assign a lower expected rate or higher risk to the deal, Hancock would still have entered into the deal. When Hancock's

management approved the deal in September 2000, it projected an average return of 17.5 percent over 15 years or, assuming it sold its future royalty stream after the fifth year, an average rate of return of 22 percent over five years. Hancock's projected rate of return on the deal also was well above the "target return" of 12.6 percent that it used to assess the performance of the investment for management performance review purposes. According to Hancock documents, around the date of the Agreement, there was a 5.13 percent yield on Treasuries and a 286 basis point spread over treasuries for investments, such as the Abbott investment, with a BA1 credit rating and average life of 15 years, therefore, the expected yield on such investments was 7.99 percent. By the time the deal was modified and executed on March 13, 2001, Hancock's expected annual rate of return on the deal had increased to 18.8 percent over 15 years, even further above its target rate of return.

Hancock had no required minimum expected rate of return for the recommendation and approval of investments such as the Abbott transaction. Mr. Nastou, the head of Hancock's Bond and Corporate Finance Department who presented the proposed deal to the Committee of Finance for approval, explained that "many times we took investments where we knew we were going to get less than [the levels we were hoping to achieve]... Because we had more money to invest than we had investments that presented themselves, and, on average, if it achieved the company's requirements, then everything worked." Mr. Nastou testified that Hancock would have declined the Abbott investment only if the expected return was "lower than anything else for the risk" available in the marketplace. Hancock entered into transactions with similar risk profiles with significantly lower expected rates of return.

80 4881848 1

Furthermore, it was not essential to the deal that the portfolio include the nine specific compounds that were actually included in the RFA. During the course of negotiations of the RFA, the proposed portfolio varied over time in both the number and phases of development of the compounds. During the negotiations, when Abbott terminated ABT-980 – a Phase III compound with a more significant impact on expected returns than earlier phase compounds – Abbott and Hancock replaced it with two early phase compounds and proceeded to finalize the deal.

In addition, under Hancock's policies and practices, "if there are material changes" to the proposed deal after approval by the Bond and Investment Committee and Committee of Finance, "it needs to be reapproved." Abbott made numerous disclosures to Hancock after the committees approved the deal in October 2000. Those disclosures did not prompt Mr. Blewitt to take the deal back to the investment committees for reapproval or undertake further due diligence. Indeed, when Mr. Blewitt drafted a memorandum to file documenting the "significant changes to the transaction compared to the initial report to the Committee of Finance", he only mentioned changes in the contract terms and did not even note the new information regarding the Program Compounds that Abbott had disclosed.

Finally, ABT-518 and, to a lesser extent ABT-594, represented only a small portion of Hancock's total investment and expected return. Even though ABT-773 was more significant, in 2002, after Abbott had terminated ABT-518, ABT-594, and ABT-773, Hancock was still accruing income on the deal over and above its "target income." John Mastromarino analyzed the deal soon after joining Hancock as Chief Risk Officer in February 2003. Although Abbott had terminated ABT-518, ABT-594, ABT-773, and

other compounds by that time, Barry Welch (the Senior Vice President of Hancock's Bond and Corporate Finance Group) told Mr. Mastromarino he remained "pretty positive" about the deal and Mr. Hartz told Mr. Mastromarino that "I thought it was a good transaction."

179. <u>Proposed Substitute Findings</u>: Hancock's expert witness, Mr. Alan Friedman, has failed to calculate Hancock's damages with reasonable certainty. Mr. Friedman's damages analysis is contrary to law and without economic foundation. Mr. Friedman's damages calculation is barred under Illinois law which prohibits the recovery of "lost profits" for new products in untested markets.

Mr. Friedman's analysis also relies on improper probability-weighted analysis to calculate lost profits. Mr. Friedman was unable to identify any other cases in which he has used a probability-weighted analysis. Although probability-weighted calculations of future revenue are used for certain purposes, they are not a proper economic method to measure damages with reasonable certainty. The articles that Hancock relied upon in support of the probability-weighted approach actually show that it is not an accepted method of proving lost profits due to alleged misrepresentations.

Mr. Friedman also failed to demonstrate that the claimed damages were caused by the alleged misrepresentation. For example, Mr. Friedman did not analyze the actual impact of the alleged misrepresentations on expected sales, simply assuming, without foundation, that the entire decline from original projections is attributable to the alleged misrepresentations. In fact, Abbott's estimated probabilities of success and projected sales were demonstrably not accurate predictors of future events (i.e., not a reliable predictor of what would have happened "but for" the alleged misrepresentations). A

proper calculation of Hancock's lost profits, if lost profits were available and if a probability-weighted calculation of lost profits were appropriate, would calculate the value of the compounds as of the date of the RFA "but for" the allegedly undisclosed negative facts, less the actual value of the compounds as of the time of the RFA in light of the negative facts.

Mr. Friedman does not properly calculate either the "but for" or the "actual" scenario. He uses as his "but for" scenario Abbott's internal projections, which would already reflect any negative information that was known to Abbott. The internal Abbott commercial forecasts that Mr. Friedman assumes represent what the compounds would have been worth "but for" the allegedly undisclosed material adverse facts, actually were updated in early 2001 (after Hancock alleges Abbott had undisclosed knowledge of adverse facts) in connection with Abbott's portfolio prioritization and budget process and reflect all adverse information known to Abbott at that time. Furthermore, Abbott further updated its forecasts for an April 2001 portfolio review meeting -- again incorporating all adverse information known to Abbott at that time -- and the revised forecasts for the compounds are virtually identical to the success probabilities projected at the time of the Agreement (used by Mr. Friedman in his "but for" scenario).

Mr. Friedman actual scenario is also improper because it is not assessed as of the date of the Agreement. Instead, Mr. Friedman uses as his "actual" scenario the status of the compounds at a later date, which reflects diminution in value due to post-contractual developments unrelated to the alleged fraud. Mr. Friedman assumed, without study and contrary to evidence, that the projections would have gone to zero based on the allegedly undisclosed adverse information known to Abbott. As noted above, however, the internal

Abbott projections Mr. Friedman uses for his "but for" scenario already consider all factors known to Abbott at the time of the Agreement and, therefore, represent the true "actual" scenario. In addition, Mr. Friedman did not analyze whether factors other than the alleged misrepresentations, such as information that became available to Abbott after March 13, 2001 (e.g., the MMPI data released at the ASCO conference, the unblinding and analysis of data from the clinical trial of ABT-594, and changes in the regulatory environment and subsequent clinical trial results regarding ABT-773), caused the compounds at issue to fail. For example, of the six Program Compounds that are not alleged to have been misrepresented, five have been terminated and current projections for the remaining compound are substantially below Abbott's projections as of the time of the Agreement. Despite a dramatic reduction in the expected sales for these compounds for reasons that Hancock acknowledges are unrelated to alleged misrepresentations, Mr. Friedman inconsistently assumes that there was no reduction in the expected sales for ABT-518, ABT-594, and ABT-773 for reasons other than the alleged misrepresentations.

In addition, Mr. Friedman's but-for scenario is inconsistent with Hancock's original claim of what would have happened in the absence of the alleged misrepresentations. Hancock's complaint alleges that had Hancock known the "true development status and prospects" of the compounds, it "would have demanded different terms, such as the substitution of another compounds with a comparable projected value or more favorable financial terms with respect to the remaining Program Compounds" or not entered into the Agreement. With the exception of his rescission calculation, Mr. Friedman did not analyze any of the circumstances that Hancock alleges would have

occurred (e.g., what compounds would have been substituted or how terms would have been altered) or how Hancock's profits, if any, under such scenarios would compare to the actual results.

Mr. Friedman's damage calculations also contain numerous other errors. For example, he uses an improperly low discount rate that fails to account for the risk of not achieving the royalties and milestone payments. He failed to offset the claimed damages to reflect the additional \$110 million in Program Payments that Hancock would have been required to make in the "but for" scenario. He failed to account for Hancock's projected revenues from out-licensing of ABT-773 to Advanced Life Sciences. Finally, his damage claims are unreasonably high in relation to Hancock's original expectations.

Mr. Tucker illustrated the significance of the errors by demonstrating the dramatic effect of correction of certain of Mr. Friedman's errors. For example, (and ignoring for discussion purposes Mr. Friedman's other errors) adjusting only for (1) Mr. Friedman's failure to consider that actual results declined materially from the original projections on compounds in the deal, but not at issue in the case; (2) Mr. Friedman's failure to properly consider the delays in anticipated launch dates experienced on the compounds under development; and (3) the improper use of a risk free discount rate, with these adjustments, Mr. Tucker calculated that the alleged lost royalty and milestone payments for all three compounds would be \$3.2 million in the Low Case and \$28.1 million in the Base Case. For illustration purposes, Mr. Tucker also calculated the impact of a hypothetical renegotiation of a royalty rate, required to maintain Hancock's originally projected internal rate of return, under a hypothetical assumption that ABT-518, ABT-594 and ABT-773 were eliminated from the portfolio in March 2001, which is

consistent with what Hancock alleges in its Second Amended Complaint would have occurred. That hypothetical scenario would generate an increase in expected royalties of \$1 million in the Low Case and \$14 million in the Base Case over and above the currently expected royalties based on the actual agreed upon rates.

Therefore, Mr. Friedman's testimony is unreliable and speculative.

- 180. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA or engage in fraud with regard to ABT-518 and Hancock has not suffered actual monetary damages with regard to this claim.
- 181. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA or engage in fraud with regard to ABT-594 and Hancock has not suffered actual monetary damages with regard to this claim.
- 182. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA or engage in fraud with regard to ABT-773 and Hancock has not suffered actual monetary damages with regard to this claim.
- 183. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA or engage in fraud with regard to the Annual Research Plans Abbott provided to Hancock, and Hancock has not suffered actual monetary damages with regard to this claim.
- 184. Proposed Substitute Findings: Abbott did not breach the contract because it had no obligation to pay Hancock pursuant to Section 3.3(b) of the RFA after Hancock was excused from making its third and fourth program payments. Hancock has not suffered actual monetary damages with regard to this alleged breach. *If Abbott were liable for a breach of Section 3.3(b), the damages would be \$28.2 million, rather than the \$33.0 million claimed by Hancock. Hancock bases its claim for \$33.0 million on the*

spending reported by Abbott in a Research Plan Funding Update dated November 20, 2007. However, Abbott subsequently informed Hancock that the report understated certain expenditures and that the correct spending numbers were contained in Abbott's amended interrogatory responses. Abbott also has produced its internal Project Expense Reports, which are generated in the ordinary course of business to track expenditures on each compound, and from which the spending amounts in the Amended interrogatory responses are derived.

- 185. <u>Proposed Substitute Findings</u>: Abbott did not breach the RFA with regard to Hancock's audit pursuant to the RFA and Hancock has not suffered actual monetary damages with regard to this alleged breach.
- 186. <u>Proposed Substitute Findings</u>: Abbott did not breach its obligations with respect to efforts to out-license or divest ABT-518 to a third party and Hancock has not suffered monetary damages with regard to this alleged breach.
- 187. <u>Proposed Substitute Findings</u>: Abbott did not breach its obligations with respect to efforts to out-license or divest ABT-594 to a third party and Hancock has not suffered monetary damages with regard to this alleged breach.
- 188. <u>Proposed Substitute Findings</u>: Hancock has not suffered any compensable Losses under the RFA.
- 189. <u>Proposed Substitute Findings</u>: Hancock has not suffered any compensable Losses under the RFA and is not entitled to prejudgment interest.

II. PROPOSED CONCLUSIONS OF LAW

Jurisdiction, Venue, and Choice of Law

- 1. No proposed substitute or additional conclusions of law.
- 2. No proposed substitute or additional conclusions of law.

3. No proposed substitute or additional conclusions of law.

Abbott Did Not Engage In Fraudulent Conduct (Count I)

- 4. Proposed Substitute Conclusions: Count I of Hancock's Second Amended Complaint (the "Complaint") asserts a cause of action against Abbott for fraud. "Under Illinois law, to establish actionable fraud, a plaintiff must prove: that defendants, with the intent to induce plaintiffs to act, made a false statement of material fact which defendants knew or believed to be false. Plaintiffs must also show they justifiably relied on the statement and suffered damages resulting from that reliance. Most importantly, fraud must be proved by clear and convincing evidence." *Ass'n Ben. Services, Inc. v. Caremark RX, Inc.*, 493 F.3d 841, 852-53 (7th Cir. 2007) (internal citations omitted).
- 5. Proposed Substitute Conclusions: Under Illinois law, a misrepresentation or omission is "material" only if the plaintiff "would have acted differently" had he been aware of it. *Perlman v. Time, Inc.*, 64 Ill. App. 3d 190, 197, 380 N.E.2d 1040, 1046 (1978); *see also North American Fin. Group, Ltd. v. S.M.R. Enters., Inc.*, 583 F. Supp. 691, 698 (N.D. Ill. 1984) (to be material, a "concealed fact must be such that had the plaintiff known the truth, he would have acted differently"); *Mack v. Plaza Dewitt Ltd. P'ship*, 137 Ill. App. 3d 343, 350-51, 484 N.E.2d 900, 906 (1985). If a misrepresented condition is relatively minor and "only one of many features to be considered" in making an investment decision, then it is not material. *Mack*, 137 Ill. App. 3d at 351.
- 6. <u>Proposed Substitute Conclusions</u>: Pursuant to the RFA, Abbott was not required to disclose "generally available information concerning the pharmaceutical industry in general." "[T]he requirement of ordinary care in discovering the truth or falsity of the representations is imposed on the party claiming fraud in order to establish justifiable reliance. The background, special expertise or education of the plaintiff also

may be considered incident to the reasonable reliance element." *See North American Fin. Group, Ltd. v. S.M.R. Enters., Inc.*, 583 F. Supp. 691, 697-8 (N.D. Ill. 1984) (internal citations omitted). "Regarding the requirement that the misrepresentation must be a past or present fact, usually mere expressions of opinion of future occurrences, especially of future profitability, are not actionable." *Id.* "Finally, regarding the materiality requirement, a misrepresentation, regardless of how intentional, cannot be material if it makes no difference. The fact must be essential to the inducement of the plaintiff's action. The concealed fact must be such that had the plaintiff known the truth, he would have acted differently." *Id.*

- 7. <u>Proposed Substitute Conclusions</u>: While Illinois generally follows the "benefit-of-the-bargain" approach to damages for fraud, "[i]t has been recognized . . . that a benefit-of-the-bargain measure may not be appropriate in all circumstances." *See Giammanco v. Giammanco*, 253 Ill. App. 3d 750, 760 (Ill. Ct. App. 1993).
- 8. Proposed Substitute Conclusions: Under Illinois law, a party claiming damage "bears the burden of proving those damages to a reasonable degree of certainty" and speculative damages are not recoverable. *TAS Distrib. Co. v. Cummins Engine Co., Inc.*, 491 F.3d 625, 632 (7th Cir. 2007). A corollary of this rule is that lost profits are not available for a new business or a new product of an existing business. *See id.*; *Stuart Park Assocs. Ltd. P'ship v. Ameritech Pension Trust*, 51 F.3d 1319, 1328 (7th Cir. 1995); *Kinesoft Dev. Corp. v. Softbank Holdings, Inc.*, 139 F. Supp. 2d 869, 908 (N.D. Ill. 2001) ("Under Illinois law, a new business, or an existing business with a new product, cannot recover lost profits because the future profits of a new business cannot be ascertained with any degree of certainty.") (internal citations omitted); *Alphamed Pharmaceuticals*

Corp. v. Arriva Pharmaceuticals, Inc., 432 F. Supp. 2d 1319, 1340 n.36 (S.D. Fla. 2006) (noting Illinois has absolute bar to recovery of lost profits under the "new business" rule). Even where a plaintiff has shown that the company has a record of success in previous endeavors, Illinois courts refuse to allow recovery of lost profits for a new product in a new market. Kinesoft, 139 F. Supp. 2d at 909-10. The Seventh Circuit in Stuart Park reached the same result when real estate partnerships sought to recover profits they allegedly lost from an apartment complex that was never built. 51 F.3d at 1328. In affirming a verdict against the partnerships, the Seventh Circuit noted that their successes with other apartment buildings were irrelevant because they were "different pieces of real estate from different markets," and provided no useful basis for comparison. Id. Put differently, the partnerships were selling different products in a new, different market. In the rare cases where lost profits have been awarded for a new business or product, courts have required evidence of an established market for the product. Milex Prods. Inc. v. Alra Labs. Inc., 603 N.E. 2d 1226, 1236-37 (Ill. Ct. App. 1992).

Since Hancock is seeking lost profits for new products—ABT-518, ABT-594, and ABT-773, which were experimental compounds never before approved or marketed—it is barred under the Illinois new business or new products rule from recovering lost profits. *See Alphamed Pharmaceuticals Corp.*, 432 F. Supp. 2d at 1345-46 ("reliance on a multitude of assumptions is endemic to any valuation of the prospective profitability of new pharmaceutical products. . . . This inherent uncertainty makes the recovery of lost profits for anticipated sales of a new drug exceedingly difficult.").

9. No proposed additional or substitute conclusions of law.

- 10. <u>Proposed Substitute Conclusions</u>: Hancock has not satisfied its burden of proving fraud by clear and convincing evidence in this case.
- 11. <u>Proposed Substitute Conclusions</u>: Based on the foregoing findings of fact, the Court concludes that Abbott did not fraudulently or intentionally induce Hancock to enter into the RFA.
- 12. <u>Proposed Substitute Conclusions</u>: The Court concludes that Abbott did not make any material fraudulent misrepresentations or omissions.
- 13. <u>Proposed Substitute Conclusions</u>: The Court concludes that Abbott did not make any material misrepresentations or omissions and Hancock did not justifiably rely on any alleged fraudulent misrepresentations or omissions by Abbott.
- 14. <u>Proposed Substitute Conclusions</u>: The Court concludes that Abbott's ARPs were complete and accurate in all material respects, and Hancock did not rely on any alleged fraudulent misrepresentations or omissions by Abbott in making its Second Program Payment in the amount of \$54,000,000 in January 2003.
- 15. <u>Proposed Substitute Conclusions</u>: The Court concludes that Abbott was not required to disclose to Hancock generally available information concerning the pharmaceutical industry in general.
- 16. <u>Proposed Substitute Conclusions</u>: The Court concludes that Hancock has not suffered actual, compensable harm.
- 17. <u>Proposed Substitute Conclusions</u>: Since Hancock has not suffered actual, compensable harm, Abbott is not obligated to compensate Hancock.
- 18. <u>Proposed Substitute Conclusions</u>: The Court concludes that punitive damages are not warranted in this case.

Abbott Did Not Breach the RFA (Count II)

- 19. <u>Proposed Substitute Conclusions</u>: Count II of Hancock's Complaint asserts a cause of action against Abbott for breach of contract. Under Illinois law, an action for breach requires: (1) the existence of a valid and enforceable contract; (2) breach of the contract by plaintiff; (3) performance of the contract by defendant; and (4) a resulting injury to the defendant (i.e., damages proximately caused by the breach). *Kinesoft Development Corp. v. Softbank Holdings Inc.*, No. 99C7428, 2000 WL 1898577, at *3 (N.D. Ill. Dec. 20, 2000).
 - 20. No proposed additional or substitute conclusions.
 - 21. No proposed additional or substitute conclusions.
 - 22. No proposed additional or substitute conclusions.
- 23. Proposed Additional Conclusions: "... Illinois law does not recognize independent claims based on breaches of any implied duties of good faith." *Echo, Inc. v. Whitson Co., Inc.*, 121 F.3d 1099, 1105-06 (7th Cir. 1997); *see also Johnstone v. Bank of America, N.A.*, 173 F. Supp. 2d 809, 817-818 (N.D. Ill. 2001) ("The Supreme Court of Illinois has held that there is no independent cause of action for breach of the duty of good faith and fair dealing.") (internal citation omitted).
- 24. <u>Proposed Substitute Conclusions</u>: Breach of an express representation or warranty only constitutes a breach of contract if all of the elements of a breach of contract claim are met, including that the plaintiff relied on the express representation or warranty. *Spectramed Inc. v. Gould Inc.*, 304 Ill. App. 3d 762, 774-75, 710 N.E.2d 1, 9-10 (1998) (a party's actual knowledge of the omitted information "may result in waiver of the contract's warranties.").

- 25. <u>Proposed Substitute Conclusions</u>: Hancock must show actual reliance on the representations. *See id.*; *Chamberlain Mfg. Corp. v. Maremont Corp.*, No. 92-0356, 1995 WL 103803, at *2 (N.D. Ill. Mar. 6, 1995) (proof of actual reliance is required under Illinois law).
- 26. <u>Proposed Substitute Conclusions</u>: While Illinois generally follows the "benefit-of-the-bargain" approach to damages for fraud, it has been recognized that a benefit-of-the-bargain measure may not be appropriate in all circumstance. *Real Estate Value Co. v. USAir, Inc.*, 979 F. Supp. 731, 740-41 (N.D. Ill. 1997).
 - 27. <u>Proposed Substitute Conclusions</u>: *Supra*, ¶ 8.
 - 28. No proposed additional or substitute conclusions.
- 29. <u>Proposed Substitute Conclusions</u>: Hancock has not demonstrated that Abbott breached the RFA by a preponderance of evidence in this case.
- 30. <u>Proposed Substitute Conclusions</u>: The Court concludes that Abbott has not breached the RFA.
- 31. <u>Proposed Substitute Conclusions</u>: The Court concludes that misrepresentations, omissions and breaches of the RFA alleged by Hancock did not result in, or could not have been expected to result in, a material adverse effect on the prospects or condition of the Research Program or any of the Program Compounds.
- 32. <u>Proposed Substitute Conclusions</u>: The Court concludes that Hancock has not suffered any harm as a result of Abbott's alleged breaches of the RFA.
- 33. <u>Proposed Substitute Conclusions</u>: Since Hancock has not suffered any damages, Abbott is not obligated to compensate Hancock.

34. <u>Proposed Substitute Conclusions</u>: The Court concludes that punitive damages are not warranted in this case.

Indemnification by Abbott (Count III)

35. <u>Proposed Substitute Conclusions</u>: Count III of Hancock's Complaint asserts a cause of Action against Abbott for indemnification pursuant to the RFA. The plain language of the RFA limits Hancock's indemnity rights to claims by third parties.

Section 12.6 of the RFA provides:

General Indemnification of John Hancock. Abbott shall indemnify and hold John Hancock and its Affiliates, agents, directors and employees harmless, and hereby forever releases and discharges John Hancock and its Affiliates, agents, directors and employees, from and against all Losses related to or arising out of, directly or indirectly, (i) any negligence, recklessness or intentional misconduct of Abbott or its Affiliates, agents, directors, employees, Subcontractors, licensees (including Licensees) or sublicensees in connection with the Research Program, Program Compounds or Products, or (ii) any manufacture, use, storage, distribution or sale of the Program Compounds or Products by anyone, including without limitation all Losses related to any personal injury or death, or (iii) any breach by Abbott of its representations, warranties or obligations hereunder, or (iv) the consummation of the transactions contemplated hereby, except, in each case, to the extent any such Losses are the result of (A) any breach by John Hancock of its representations, warranties or obligations hereunder, or (B) any negligence, recklessness, or intentional misconduct by John Hancock or its Affiliates, agents, directors, employees.

Section 12.8 of the RFA provides the procedure by which Hancock may claim indemnification:

<u>Procedure</u>. If John Hancock or any of its Affiliates, agents, directors or employees (<u>each</u>, an "<u>Indemnitee</u>") intends to claim indemnification under this Article 12, it shall promptly notify Abbott (<u>the "Indemnitor"</u>) of any Loss or action in respect of which the Indemnitee intends to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the

extent the Indemnitor so desires, to assume the defense thereof with counsel selected by the Indemnitor; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses of such counsel to be paid by the Indemnitor, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. The indemnity obligation in this Article 12 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably or delayed. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any such action, if materially prejudicial to its ability to defend such action, shall relieve the Indemnitor of any liability to the Indemnitee under this Article 12 only to the extent arising from the tardiness or absence of such notice, but the omission so to deliver notice to the Indemnitor will not relieve it of any liability that it may have to any Indemnitee otherwise than under this Article 12. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by indemnification under this Article 12, at the expense of the Indemnitor.

36. <u>Proposed Substitute Conclusions</u>: Section 1.27 defines "Losses" as "any claims, demands, liabilities, costs, damages, judgments, settlement *and* other reasonable expenses (including attorneys' fees)." In construing a contractual indemnity provision, the goal is to ascertain and give effect to the parties' intent. *Eichengreen v. Rollins, Inc.*, 325 Ill. App. 3d 517, 521, 757 N.E.2d 952, 956 (Ill. App. 2001).

"An indemnity agreement is an agreement whereby the indemnitor agrees to protect the indemnitee from claims asserted against the indemnitee by third persons." *Magnus v. Lutheran General Health Care System*, 235 Ill. App. 3d 173, 185, 601 N.E.2d 907, 915 (Ill. App. 1992); *Ferguson v. Wozniak Industries, Inc.*, 931 S.W.2d 919, 923 (Mo. App. S.D. 1996) ("In general, an agreement to indemnify another is an agreement by one person to hold another harmless from loss or damage as may be specified in the

Page 96 of 103

agreement or in which the indemnitor promises to reimburse his indemnitee for loss suffered. Under Illinois law, that loss is generally associated with liability to a third person.") (citations omitted).

- 37. Proposed Substitute Conclusions: The Court concludes that Hancock did not suffer compensable Losses in this case. The Court also concludes that the Indemnity Provision of the RFA is limited to indemnification for third-party claims and is not applicable to Hancock's claims against Abbott.
- Proposed Substitute Conclusions: Since the Indemnity provision is 38. inapplicable to Hancock's claims and Hancock did not suffer compensable Losses in this case, Abbott is not obligated to indemnify Hancock.

Hancock is Barred from the Alternative Remedy of Rescission (Prayer (e))

- 39. Proposed Substitute Conclusions: Rescission is an equitable remedy to which plaintiffs are never entitled as a matter of right. Luciani v. Bestor, 106 Ill. App. 3d 878, 882, 436 N.E.2d 251, 254-55 (1982). See also Pension Benefit Guar. Corp. v. Ziffer, No. 91C7762, 1994 U.S. Dist. LEXIS 87, *28 (N.D. Ill. Jan. 4, 1994) ("[d]ifferent considerations are taken into account as part of [an] inquiry into whether a contract should be rescinded"); Giacomazzi v. Urban Search Corp., 86 Ill. App. 3d 429, 432, 407 N.E.2d 621, 623-24 (1980) (factual issues such as "reliance, materiality, due care, knowledge, and intent of the parties" are relevant); see also Pension Benefit, 1994 U.S. Dist. LEXIS at *28 (a plaintiff seeking rescission must demonstrate both actual and reasonable reliance).
- 40. Proposed Additional Conclusions: Hancock's claim for rescission is barred by the limitations of remedies provision in the RFA. See Abbott's Post-Trial Supp. Proposed Findings of Fact and Concl. of Law, paragraphs 1-64, filed on April 23,

2008 (addressing Sections 11.2 and 11.3 of the RFA).³ Hancock is also barred from rescinding the RFA under the doctrines of waiver and judicial estoppel. *Id.* at 1-60, 69-127. (Although Abbott has set forth its argument that Hancock is not entitled to rescission in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law in an excess of caution, Hancock bears the burden of establishing a right to the equitable remedy of rescission (including the burden of showing that its delay and affirmation of the RFA, after knowledge of the alleged fraud, and the limitation of remedies provision of the RFA, do not preclude its claim for rescission).)

- 41. <u>Proposed Substitute Conclusions</u>: The Court concludes that Abbott did not breach the RFA or engage in fraudulent conduct, and that the misrepresentations and omissions alleged by Hancock are not material and not of such a nature that the RFA would not have been made without them.
- 42. <u>Proposed Substitute Conclusions</u>: The Court concludes that Hancock is not entitled to the alternative remedy of rescission.

Abbott's Affirmative Defenses

<u>Proposed Substitute and Additional Conclusions</u>: Paragraphs 43-71 of Hancock's Proposed Findings of Fact and Conclusions of Law are addressed by Abbott's Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law, filed on April 23, 2008.

³ Pursuant to the Court's Second Amended Order Regulating Non-Jury Trial, each party is required to file Proposed Findings of Fact and Conclusions of Law on any claim or defense for which it has the burden of proof. Abbott's Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law sets forth Abbott's argument that Hancock is barred from rescinding the RFA under the doctrines of waiver and judicial estoppel. Abbott does not concede, by including this argument, and other arguments, in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law, that it bears the burden of proof on these issues. However, in an abundance of caution, Abbott has included the arguments in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law.

72. <u>Proposed Substitute Conclusions</u>: Judgment shall enter in favor of Defendant Abbott Laboratories.

Abbott Was Not Required to Spend \$614 Million on the Program Compounds After Hancock Was Excused From Making Its Third and Fourth Program Payments

73. Proposed Additional Conclusions: Under Illinois law, "[i]t is well settled that a court, when construing a contract, should ascertain the intent of the parties and give effect to that intent." *Eichengreen v. Rollins, Inc.*, 325 Ill. App. 3d 517, 521, 757 N.E. 2d 952, 956 (1st Dist. 2001) (citing *In re Marriage of Olsen*, 124 Ill. 2d 19, 25-26 (1988). When interpreting the terms of a contract, a court "must consider the document as a whole, rather than focusing on isolated portions." *Premier Title Co. v. Donahue*, 328 Ill. App. 3d 161, 164, 765 N.E. 2d 513, 516 (2nd Dist. 2002). "It is fundamental in contract construction that, if possible, effect must be given *to all of the language* so that provisions which appear to be conflicting or inconsistent may be reconciled or harmonized." *In re Halas*, 104 Ill.2d 83, 92, 470 N.E.2d 960, 964 (Ill. 1984) (emphasis added).

Under Illinois law and standard rules of contract interpretation, the RFA does not require Abbott to spend \$614 million in the event that Hancock is excused from making its Program Payments. *See supra*, Findings of Fact, ¶¶ 141-53.

74. <u>Proposed Additional Conclusions</u>: The doctrine of judicial estoppel "precludes a party from asserting a position in one legal proceeding which is contrary to a position it has already asserted in another." *Patriot Cinemas, Inc. v. General Cinema Corp.*, 834 F.2d 208, 212 (1st Cir. 1987); *see also New Hampshire v. Maine*, 532 U.S. 742, 749 (2001). For judicial estoppel to attach, two condition must be satisfied. First, "the estopping position and the estopped position must be directly inconsistent, that is,

mutually exclusive." *Alternative Sys. Concepts, Inc. v. Synopsy, Inc.*, 374 F.3d 23, 33 (1st Cir. 2004). Second, "the responsible party must have succeeded in persuading a court to accept its prior position." *Id.* Together, the presence of these two elements gives the impression that "either the first court has been misled or the second court will be misled, thus raising the specter of inconsistent determinations and endangering the integrity of the judicial process." *Id.*

- 75. Proposed Additional Conclusions: Hancock's claim pursuant to Section 3.3(b) is premised on the assumption that Abbott must spend the \$614 million irrespective of Hancock's payments. Hancock took a contrary position in *Hancock I*, arguing that the Aggregate Spending Target represents the "combined total" of the parties' defined minimum and maximum contributions, i.e., \$400 million from Abbott and approximately \$200 million from Hancock, and that the very purpose of the Agreement was for them to share the financial burdens of pharmaceutical development in that two-to-one ratio.
- 76. <u>Proposed Additional Conclusions</u>: Hancock is judicially estopped from arguing that it is entitled payments pursuant to Section 3.3(b) of the RFA.
- 77. Proposed Additional Conclusions: "Contract interpretations that produce commercially unreasonable results are disfavored, not as a matter of policy but simply because they are implausible to impute to the parties." *XCO Int'l, Inc. v. Pacific Scientific Co.*, 369 F.3d 998, 1005 (7th Cir. 2004). "[I]t is a fundamental principle of contract interpretation that courts read language to make business sense whenever possible." *Gerow v. Rohm & Haas Co.*, 308 F.3d 721, 725 (7th Cir. 2002). Hancock's interpretation of Section 3.3(b) of the RFA would produce a commercially irrational

result that the parties could not have intended. *See* Abbott's Post-Trial Supp. Prop. Findings of Fact and Concl. of Law, filed April 23, 2008, ¶¶ 142-51.

In addition, Section 3.3(b) of the RFA, as interpreted by Hancock, is an invalid and unenforceable penalty provision under Illinois law, Hancock's claim pursuant to Section 3.3(b) of the RFA is barred under Illinois law. *See* Abbott's Post-Trial Supp. Prop. Findings of Fact and Concl. of Law, paragraphs 65-68 and 128-163.⁴

Abbott Was Not Required to Provide Hancock With Its Risk-Adjusted Expected Spending in Its First Annual and Subsequent Annual Research Plans Pursuant to Section 3.4(iv) of the RFA

78. <u>Proposed Additional Conclusions</u>: The RFA defines the ARP as

reasonably and consistently detailed statement of the objectives, activities, timetable and budget for the Research Program for every Program Year remaining in the Program Term

Abbott represented that the first ARP provided a

a description of projected milestones and dates thereof, projected year of NDA filing, and projected costs to be incurred by Abbott during the Program Term, for each Program Compound. Such projections were prepared in good faith and with due care based on reasonable assumptions, and represent the reasonable estimate of Abbott based on information available as of the date of such projections and as of the date hereof; if being agreed that such projections do not constitute any warranty as to the future performance of the Program Compounds and that actual results may vary from such projections.

⁴ Pursuant to the Court's Second Amended Order Regulating Non-Jury Trial, each party is required to file Proposed Findings of Fact and Conclusions of Law on any claim or defense for which it has the burden of proof. Abbott's Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law sets forth Abbott's argument that Hancock's interpretation of Section 3.3(b) would constitute an unenforceable penalty. Abbott does not concede, by including this argument, and other arguments, in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law, that it bears the burden of proof on these issues. However, in an abundance of caution, Abbott has included the arguments in its Post-Trial Supp. Proposed Findings of Fact and Conclusions of Law.

Abbott's ARPs provided Hancock with Abbott's "budget" and "projected costs" for the Program Term. The RFA did not require Abbott to provide Hancock with its riskadjusted expected spending in its First ARP or its subsequent ARPs, including the ARP for 2002. Pursuant to Section 3.4(iv) of the RFA, Abbott

reasonably demonstrate[d] in its Annual Research Plan its intent and reasonable expectation to expend in Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target.

Therefore, Hancock was not excused from making its first and second Program Payments to Abbott.

Dated: April 23, 2008 Respectfully submitted,

Document 384

ABBOTT LABORATORIES

By: /s/ Jeffrey I. Weinberger_

Jeffrey I. Weinberger (pro hac vice) Gregory D. Phillips (pro hac vice) Eric J. Lorenzini (pro hac vice) Ozge Guzelsu (pro hac vice) MUNGER, TOLLES & OLSON LLP 355 South Grand Avenue, Thirty-Fifth Floor Los Angeles, CA 90071-1560 Telephone: (213) 683-9100

and

Peter E. Gelhaar (BBO#188310) Michael S. D'Orsi (BBO #566960) DONNELLY, CONROY & GELHAAR LLP 1 Beacon St., 33rd Floor Boston, Massachusetts 02108 (617) 720-2880 peg@dcglaw.com msd@dcglaw.com

Counsel for Abbott Laboratories

CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on April 23, 2008.

Date: April 23, 2008.	
	/s/ Eric J. Lorenzini